EXHIBIT E

Gynecare PROLIFT*

Pelvic Floor Repair Systems

SURGEON'S RESOURCE MONOGRAPH

Approved

APR 13 2007

Marketing Services

Foreword

This monograph affords the reader a unique opportunity to have access to the experience of surgeons from around the world who have each performed the GYNECARE PROLIFT* Pelvic Floor Repair System procedure in a large number of cases. Much of the information was culled from a series of user forums held in several cities in the US, Europe and Australia. The rest is the collective experience of the authors including Michel Cosson, Christl Reisenauer, Jim Raders, Doug Van Drie, David Robinson, Vince Lucente and myself.

In the course of literature review on new procedures, it is often difficult to obtain information on patient selection, complications, technique refinements, and outcomes. Case series have an inherent weakness in that they represent the experience of surgeons in a specific limited number of cases. Less common complications or ones that may occur only in less experienced hands will often go undiscussed. This document is an open exchange of ideas representing the most up-to date information possible. The perspective that must be kept in mind is that it is information that is not available on most procedures, and even single cases out of the large number of total GYNECARE PROLIFT System procedures performed are honestly presented. All surgical procedures have complications and experience-related consequences are seen in even the most basic gynecologic surgeries.

We are in a relatively unprecedented era of change in the operative management of Pelvic Organ Prolapse. Over the last 40 years little has changed in surgeons' options. The reasons for this are varied. Comparative outcome studies on traditional vaginal repairs have been lacking and long-term follow-up is, in general, incomplete. Much of the data on traditional vaginal repairs is contradictory and there is evidence that nearly 1 in 3 operations for prolapse is for previous failure. Nonetheless, we have continued to perform vaginal approach repairs that are well known to be unsatisfactory. The abdominal approach to POP provides more reason to be optimistic but remains only a fraction of the total number of procedures done in the world. The abdominal sacrocolpopexy is never going to be the sole form of treatment for all patients with prolapse. It is with this as the backdrop that surgeons from around the world began to assess innovative options previously unavailable. Synthetic mesh grafted repairs have been around since the 1980's and it could be argued that the ASC is simply an abdominal delivery system for a grafted repair. The success of the ASC is, in fact, more likely due to its grafting than to the sacral fixation.

Nine accomplished French surgeons formed a study group to evaluate the potential for incorporating an adjustable winged delivery system into the grafted approach to overcome the inherent shortcomings in suture-fixated transvaginal grafts. This 2-year process was unique and successful in creating a procedure designed for and by surgeons. Its adoption has been helped by the fact that it really is a combination of technologies already becoming familiar to surgeons during this same time period.

They made a prudent decision to begin to track all operative data, including complications, from the outset. This accumulated into 687 patients by 2005. This was followed by a multicenter trial involving 180 patients with 1-year follow-up. To the credit of ETHICON Women's Health & Urology, all of this preceded the commercial release of GYNECARE PROLIFT System in March 2005. In post-market evaluation, at least 7 case series have been initiated. A recent study published in Obstetrics and Gynecology by the Nordic transvaginal mesh group demonstrates that the rate of perioperative complications with GYNECARE PROLIFT System is very low. Twenty-five centers registered all patients undergoing GYNECARE PROLIFT System prospectively, which assures that patients with bad outcomes did not go unreported and that results are reproducible in many surgeons' hands. This is a model for other surgical equipment manufacturers to emulate.

This is not to say that the work is done. Outcome data and comparative data over long periods of time are needed. Throughout the POP surgery literature the weakest outcome measure is always the impact of surgery on sexuality. The look at GYNECARE PROLIFT System in this regard is incomplete. The early data is promising and the collective reports of experienced surgeons has been very favorable. Each of the case series reporting on the TVM/ GYNECARE PROLIFT System procedure has collected data on dyspareunia and the short-term rates have been uniformly low.

Dennis Miller, MD

Expert opinions on the use of GYNECARE PROLIFT SYSTEM* Total, Anterior, and Posterior Pelvic Floor Repair System

Introduction

GYNECARE PROLIFT SYSTEM consists of a trocar delivery system to streamline the placement of a precut piece of GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh in the anterior and/or posterior vaginal compartments, when symptomatic prolapse requires surgical intervention. To date, over 35,000 procedures have been performed worldwide and 7 known case series are in progress with at least interim results. All surgical procedures have risks and complications. Those discussed here should be understood in the context of the published complications of all surgery for pelvic organ prolapse. This report is a summary of the collective experiences of the most experienced GYNECARE PROLIFT SYSTEM users who were invited to attend one of 5 GYNECARE PROLIFT SYSTEM user forums held throughout the world. The comments and opinions contained within this document represent the experiences of the 10 authors as well as over 200 participating international prolapse surgeons.

Patient Selection

GYNECARE PROLIFT SYSTEM is useful in any patient that a surgeon feels would require synthetic graft augmentation. Only the treating surgeon can determine where it is best used, although in patients with previous failure, patients with risk factors for failure, and/or the most severe degree of prolapse it has been very successfully employed and has the clearest indications.

It is a procedure of low invasiveness that can generally be performed in less than 2 hours. This means that it can be utilized in patients with a broad range of medical conditions, but surgeons have used caution in patients at either extreme age or in poor medical health.

Nonetheless, there are no absolute age restrictions. It has been used in patients under 40 and over 90 and each case has to be guided by experience and the clinical setting.

A well-estrogenized vaginal wall is preferred and a poorly vascularized vaginal wall is an intuitive concern. At the same time, users have reported good results in atrophic patients and, even when vaginal erosions due to externalized stage 3-4 prolapse are present, patients generally do well and no preoperative vaginal erosion site has been reported to be associated with postoperative healing issues or mesh exposure.

GYNECARE PROLIFT SYSTEM is contraindicated in few situations. Because the PROLENE Mesh will not stretch significantly, this procedure should not be performed in patients with future growth potential, including women with plans for pregnancy. Past history of vaginal radiation is a relative contraindication as well. Patients on anticoagulation agents undergoing surgery using GYNECARE PROLIFT SYSTEM must have their anticoagulation therapy carefully managed.

The consensus of the attendees to the GYNECARE PROLIFT SYSTEM user forums has been that the rate of dyspareunia is low. Many surgeons are finding that it has lower rates of dyspareunia than historical procedures such as the posterior colporrhaphy. The available early case series support this notion. Nonetheless, data on the impact of this procedure on sexual function is still being collected and so there are surgeons who have placed some restriction on its use when this is a concern. It is also the reason given by some to cut the GYNECARE PROLIFT SYSTEM into 2 pieces before placement to minimize the impact of mesh across the apex.

Preparation

Infection rates have been exceptionally low and only typical antibiotic prophylaxis is required. Infectious disease specialists would favor only a single dose of a first generation cephalosporin given 1 hour before surgery for this category of procedure. That being said, in the presence of prosthetic implants many experts opt for the addition of 2 doses of postoperative antibiotics as well. Monofilament polypropylene does not absorb moisture and therefore soaking the mesh in an antibiotic solution is expected to have little benefit. The use of intra-operative antibiotic irrigation is a surgeon preference but is not widely utilized by GYNECARE PROLIFT SYSTEM users.

Evidence regarding the usefulness of preoperative vaginal estrogen is lacking, although it is commonly utilized when time permits and patients agree. A simple enema the night prior surgery is recommended. Urinary and vaginal infections should be excluded. Pessaries can be removed at any time before surgical prep but if they are causing irritation or erosion of the vaginal wall, they should be removed remotely from the procedure to allow time for healing. Immunosuppression medications, including those commonly used to treat rheumatoid arthritis, should be held before and after the surgery to reduce the risk of mesh and/or surgical site infection.

Surgical Technique

Patient positioning is important for the correct insertion of the cannulae. It is also critical for the prevention of nerve injury and postoperative musculoskeletal pain. Patients are positively identified and often placed in dorsal-lithotomy while awake. The table is kept level to allow proper orientation as to the location of the obturator membrane.

It is useful to palpate the bony landmarks at the start of the procedure. Patient positioning is often asymmetrical and this needs to be accounted for in cannula placement. In addition, patients vary widely in their pelvic shape. It is useful to note the relationship between the ischial tuberosities, anus, vaginal introitus and the table. A surgeon can even mark the location of the bony landmarks on the skin prior to incision and note the asymmetries. Hyperflexion is tempting to increase the surgical exposure and was previously thought to help keep the obturator neurovascular bundle further from the needle passage. This was often discussed early in this decade with regard to obturator slings. Experience has shown that this is of little consequence during placement of the GYNECARE PROLIFT SYSTEM cannula and, on the contrary, hyperflexion may be associated with increasing levels of postoperative pain and possibly injury. Allen-type stirrups are known to provide excellent leg support for the prevention of nerve injury but are at times impractical for surgical exposure during cannula placement. Placement of lower extremity sequential compression devices during initial positioning is advised in older patients and patients with known risk factors for DVT formation.

Anesthesia and Hydrodissection

The choice of anesthesia is not affected by this procedure and there are surgeon reports of performing under moderate sedation. Local anesthesia is strongly encouraged primarily for the very positive impact it has on dissection. Historical teaching in vaginal surgery effectively emphasized splitting the fibromuscular coat of the vaginal epithelium to allow the creation of a plication layer. Even today, most surgeons employ a very thin dissection of the vaginal wall, which devascularizes the epithelium and provides no positive impact in this technique. Histologically, there is a potential space of the most loose irregular connective tissue below the vaginal fibromuscular coat, often called the true vesicovaginal and rectovaginal spaces. Learning this technique in the operating room with surgeons experienced in accessing these spaces vaginally may be critical to maintaining the low rates of mesh exposure seen by experienced GYNECARE PROLIFT SYSTEM users. Hydrodissection will preferentially go into the path of least resistance and therefore "find" this potential space if 30-60 cc is injected directly into it. One subtle technique commonly employed is to take note of the effect of the injection on the epithelium. If you are in the proper location you will not see significant blanching nor the formation of an intraepithelial wheal. The composition of the injection can be either local anesthetic, Pitressin or saline. Dilution is employed if the volume needed will exceed the maximum allowed for that agent. Initial consultation with the anesthesiologist is recommended. It may also impact on the nature and amounts of agents that they administer during the case.

Incisions

It has been previously discussed that the incisions need to traverse the full thickness of the vaginal fibromuscular wall. It is considered a critical point in closing the colpotomy incision that no trimming of the vagina be done. As a result of the outstanding vaginal lengths achieved with this surgery, vaginal trimming is counterproductive and theoretically may lead to increased rates of dyspareunia. The length of the incision is less important. The incision is commonly 3-5 cm and only needs a minimum requirement of allowing insertion of 2 fingers. The incision should avoid the erosion-prone apex and overhandling of the incisional edge is wise. The location of the incisions varies according to compartment and surgeon preference. Incision in the middle third of the vaginal wall dissects more easily and assists in development of bloodless planes. On the posterior wall, the lower third is fused with underlying pubovisceral fibers and perineal body. This makes dissection in this segment more tedious and is often unnecessary. Even among experienced GYNECARE PROLIFT SYSTEM users there is a lack of agreement about the need for perineal body incorporation. Many surgeons have found that when the upper two thirds of the vagina are well supported, the inclusion of a perineal repair becomes unnecessary and a source of additional postoperative pain. Fortunately, there is nothing in the design that precludes a perineal incision and whatever type of distal repair deemed necessary by the operating surgeon.

It is worth mentioning that some have found a distal transverse incision useful as an alternative to the longitudinal approach, particularly in the posterior compartment.

Uterine Conservation

Like many issues in prolapse surgery, this remains controversial and the literature is not yet able to provide a definitive answer. One thing is becoming clear. Simultaneous hysterectomy is associated with a significant increase in anterior mesh exposure, especially when the 2 incisions are contiguous. In addition, while hysterectomy complications are uncommon in experienced hands, they represent the majority of complications seen with this procedure. This increases the appeal of uterine conservation. It has been more common in the Europe for the last half decade and experience has been good. Experienced GYNECARE PROLIFT SYSTEM users have a very favorable view of preservation of the uterus and GYNECARE PROLIFT SYSTEM lends itself to this very well.

There are a few technique "pearls" that have helped. It is important to securely attach the distal cervix to the mesh. If a total GYNECARE PROLIFT SYSTEM is performed, the mesh is cut into 2 pieces and secured with polypropylene stitches. The posterior apical portion of the mesh is shortened and deeply placed sutures are used into the cervical stroma. Elongated or large diameter cervixes present a unique problem. Either hysterectomy is chosen in those patients who accept the increased surgical risk of adding a hysterectomy, or a trachelectomy may be employed. A modified LEEP procedure has also been used in this setting. It is more difficult to get support of the preserved uterus purely by the anterior approach alone but works particularly well when attached in the same manner in both compartments. GYNECARE PROLIFT System is the best-suited mesh kit for this task and the close proximity of the wing insertion site to the apical attachment is its best asset for this task.

Additional Sutures

The original French design of the Total Vaginal Mesh Technique (TVM) utilized fewer additional stitches and it remains that way for those surgeons. They saw the best results, with the lowest untoward effects, when fewer additional stitches were used. It is strongly recommended that no plication stitches be used under the mesh.

However, for those who have adopted GYNECARE PROLIFT System since its commercial release, there are several sutures commonly employed. The distal posterior end of the mesh is tacked into place, usually at the upper end of the perineal body or over the rectovaginal septum. When a perineorrhaphy is performed, it begins distal to the end of the mesh, although there have been those who report good results incorporating the end of the mesh into the perineorrhaphy repair.

Anteriorly, it is often helpful to place a midline absorbable stitch distally to assist in correct orientation of the mesh, avoid mesh redundancy or overlap and to prevent "rolling" of the distal graft during incorporation. In the absence of a uterus, the use of apical stitches is variable and opinions are divided. When used, they are best attached to a midline dense connective tissue such as the ends of the uterosacral/cardinal ligament complex on both left and right.

Mesh Handling

The GYNECARE PROLIFT SYSTEM mesh has the same characteristics as GYNECARE GYNEMESH PS. A lightweight macroporous, monofilament polypropylene has been shown to be the best-tolerated mesh available to clinicians today. The precut size and shape represents years of surgical innovation and engineering. While inexperienced surgeons initially may look for smaller pieces of mesh, the larger piece of mesh is necessary to prevent bearing down on the vaginal capacity during healing. The collagen-dominant layer that invests the mesh will contract over time and cause an estimated 10-20% contraction. This is why it is important to avoid excessive mesh trimming intraoperatively. Since most surgeons do not bring the mesh all the way down to the perineum, the distal osterior mesh body is generally shortened. Anteriorly, small amounts of individualizing can be done. The lateral edges can be scalloped as needed in women with contracted, narrow pelvises.

The most common mesh adjustment is the process of splitting the total GYNECARE PROLIFT System into 2 pieces, even in the absence of a uterus. This theoretically reduces the potential of "blunting" of the apex and allows insertion of a total mesh without having to tunnel around the apex. Tunneling may result in entry into the peritoneal cavity, which then requires closure. This is contrasted with the benefits of keeping the mesh intact, which include the theoretical reduction of "gap" failures with subsequent enterocele formation and may assist in pulling the mesh edge all of the way to the apex. This decision is surgeon specific and is individualized based on patient anatomy.

Technique Pearls

The cannula and retrieval device are well engineered and easy to use. The primary purpose of the cannula is to prevent linear tearing in the muscle through which it passes. The cannula should be handled with that in mind and kept stationary to avoid displacement. The design of the trocar allows for surgeons to pass the mesh through the actual sacrospinous ligament posteriorly and immediately adjacent to the ischial spine on the deep anterior pass. This is a laudable goal and new GYNECARE PROLIFT SYSTEM surgeons should strive to always reach these points. This provides the least potential for compromise of vaginal length and sets GYNECARE PROLIFT System apart from its competitors. The blue retrieval device can be made to pass along the surgeon's interdigital groove between the fingers inserted to guide it during retrieval. If this is not possible, the end can be trapped between 2 fingers and pulled out. A long tonsil clamp can also be employed to trap the suture between one finger and the backside of the clamp if the dissection spaces do not allow for two-finger placement. Others prefer to visually guide the retrieval device to the introitus by way of Breisky retractors and forceps. No matter which method is employed, the unique memory of the strand assists in easing it out of the vagina. When placing the posterior GYNECARE PROLIFT System cannulas through the sacrospinous ligament, stay 2-3 centimeters medial to the spine to reduce any potential of nerve injury.

Tension-free mesh placement is of great importance and is easily learned. There are several guidelines to keep in mind. While initial adjustment is incrementally done while the mesh is inserted, the final mesh adjustment is not done until the incisions are closed. In fact, since it is not uncommon to "over pull" on the mesh wings, they will often retract slightly as the vaginal apex is pushed cephalad during final adjustment. This loose placement of mesh is often counterintuitive to the first time surgeon but is valuable in maintaining vaginal length and caliber during the healing phase. It is important to maintain the lack of tension at the site where the mesh wing enters the muscle. This local spot can be prone to postoperative pain if the wing junction wedges into the opening. The superficial anterior wing may be sensitive to over tightening as well and its position close to the bladder neck could result in urinary retention. Posterior graft adjustments must not compromise the rectal lumen as it passes anterior to this structure. Rectal examination during placement and final adjustments assist in this endeavor. Elevating the apex to reduce any overtensioning during final adjustment is the critical element to avoiding lingering postoperative pain issues. Should it be needed, loosening of the posterior mesh can be carried out via rectal exam upon completion of the procedure.

Concomitant Procedures

It is unclear what percentage of GYNECARE PROLIFT System procedures involve both compartments, but it is common to utilize GYNECARE PROLIFT System in the most at-risk compartment and treat the other side with a traditional repair or leave it untreated in the absence of prolapse. The advantage of this approach is to reduce the mesh load and to avoid "over-treatment". The disadvantage is that it is estimated that 30% of all recurrences are actually uncovering of occult defects and the side untreated with mesh may be prone to failure as it takes a greater percentage of the valsalva forces over time.

GYNECARE PROLIFT System is not a treatment for stress incontinence and it should not be modified in an attempt to make it do so. However, sling procedures accompany GYNECARE PROLIFT System in the majority of cases for both manifest stress incontinence as well as treating occult incontinence. TVT-O is employed without difficulty but it is recommended that the cannulae stay in place while the sling is passed to avoid displacing the other mesh. The sling is generally done second and is adjusted after the prolapse is reduced after restoration of the apical and anterior wall anatomic relationships.

Cystoscopy should be considered whether a sling is performed or not to evaluate for direct bladder trauma as well as normal ureteral efflux. Though highly unusual, ureteral "kinking" from compression from the superficial mesh wing has been described in one case after efflux was not seen on one side. IVP immediately after GYNECARE PROLIFT placement confirmed unilateral ureteral obstruction and the obstruction and was easily corrected by relaxing the tension of the mesh on the affected side. The incidence of bladder or ureter injury is likely to be exceptionally low but is significantly more morbid if missed before leaving the operating room. This assessment has been supported recently in the literature by the Nordic Transvaginal Mesh Group. Each surgery is unique and the decision to perform cystoscopy is at the surgeon's discretion. If performed, carry out cystoscopy with the cannulae still in place, for ease of recognition.

Postoperative Care

The vagina is packed before leaving the OR and generally left until the following morning Though no direct evidence has shown an improved efficacy, some surgeons use longer periods, leaving vaginal packing in place for up to three days for it's potential to encourage mesh incorporation during the initial healing process and possibly reduce hematoma formation. GYNECARE PROLIFT System is fortunately not associated with significant pain and patients can be discharged the following day. Return to spontaneous voiding is usually rapid as is resumption of normal activities of daily living. Surveys have shown that postoperative lifting and activity restrictions after prolapse surgery are quite variable. An animal model suggests that after 2 weeks a significant amount of force is required to displace a mesh wing. Only constipated bowel movements are likely to produce markedly elevated intra-abdominal pressure. Nonetheless, the vast majority of surgeons recommend at least 6 weeks of heavy exertion restriction as well as a prohibition regarding intravaginal sex.

Complications

There are 7 active case series with interim results available. Complication rates within those series are low and will be reviewed. Some attempt at the collection of individual case complications has been made as well. The most notable complications are listed below

Intra-operative

- Hemorrhage
- Visceral injury
- Ureteral obstruction

Postoperative

- Hemorrhage
- Hematoma
- Fistula
- Infection
- Urinary Retention
- Mesh Exposure
- Mesh Erosion
- Dyspareunia
- Vaginal Pain

Hemorrhage

Bleeding as a direct consequence of trocar placement is unreported to date. Generally, bleeding encountered is a result of the dissection that you would do at any extensive prolapse repair. When the correct plane is entered there is often little bleeding during the procedure. There are reports of hard-to-reach vessels causing extensive blood loss. Pursuing the generalized bleeding sometimes encountered is often ungratifying and success is achieved by packing the affected side and continuing on with the contralateral side. Often the most effective relief is by getting the mesh secured into place. Hand pressure for 5 minutes has been employed if too brisk to pack away with or without the use of agents like Flo-Seal. There have been a limited number of cases where postoperative bleeding resulted in consultation with Interventional Radiology with successful embolization of an identifiable vessel. Most surgeons are quite reluctant to take a patient back to the operating room for bleeding or hematoma. The results are rarely satisfying and should be considered only when other alternatives are exhausted and hemodynamics force intervention. Hematomas are almost always self-limited and probably silently occur without incident in the occasional patient as well. Intervention is unwise unless it becomes infected or progression makes it inevitable.

Visceral Injury

In the event of an intraoperative rectal injury simple primary repair is undertaken with multiple layer closure. While many of the injuries still leave a clean field, it is recommended that the placement of mesh following an enterotomy be abandoned. It once again needs to be stressed that with adherence to the principles of the procedure, rectal injury related to trocar placement is unlikely. These injuries will occur during standard vaginal dissection common to all pelvic reconstruction. Rectovaginal fistulas have been reported with unrecognized rectal injury. It is noteworthy that in a reported case the fistula did not cause any infection of the mesh, despite its close proximity, and repair was uncomplicated.

Bladder injury during dissection has likewise been reported. Surgeons have described performing an uncomplicated watertight multilayer closure and have proceeded with the GYNECARE PROLIFT System. Despite these reports from experienced surgeons, it is recommended that consideration for abandoning the GYNECARE PROLIFT System be made since it would increase the complexity of subsequent repair if healing were not successful. It is also unclear if it would increase the likelihood of subsequent mesh complication.

Ureteral injuries have been encountered. Patients with advanced prolapse have tortuous and displaced ureters. It is with this in mind that cystoscopy, with visualization of urine coming from the ureteral orifices, should be made during each GYNECARE PROLIFT System, particularly in cases of advanced prolapse. Even if efflux of urine is seen bilaterally at the time of surgery, any symptoms suggestive of ureteral obstruction must be investigated postoperatively.

Infection

There have been very few known cases of infection related to GYNECARE PROLIFT System. In this rare event, the mesh often will need to be extracted, although it is assisted by a lack of ingrowth surrounding infected tissue. There is literature to support the conservative management of infections when in the presence of monofilament polypropylene. In the case of a perirectal abscess, for example, consideration could be made of incision and drainage with administration of broad-spectrum antibiotics.

Mesh Complications: Erosion, Exposure and Extrusion

There is no uniformity of terms used for mesh complications. The term "extrusion" should probably be avoided because it implies a known cause where mesh is forced through the surface when in fact the etiology is rarely known. "Erosion" and "exposure" are the most appropriate terms and although they are, in fact, similar in definition, it may be wise to reserve the term erosion for the more serious visceral erosion. This would help avoid confusion. Work is currently being done by a multinational task force in the standardization of terminology and definitions related to graft healing abnormalities. There are few reported cases of visceral erosion. Based on the early experience of a large number of surgeons and the available case series, visceral erosion is likely to be an exceptionally uncommon occurrence. More than likely when seen it will be the result of surgical misadventure with intra-operative penetration of the injured organ. The only other logical recommendation for prevention of visceral erosion is to avoid any compression and/or tension on adjacent organs within the compartment and place the mesh in the proper tissue plane. This is most relevant regarding rectal compression during posterior GYNECARE PROLIFT System.

This is to be contrasted with the known occurrence of simple vaginal mesh exposure. It occurs in approximately 3 - 17% of cases. Experience and avoiding hysterectomy when possible will reduce the rate to 1 - 6%. Exposure may spontaneously resolve if seen in the first 6 weeks but seems unlikely to resolve if seen after that time. They are often asymptomatic and require no treatment in that case. Experience has demonstrated though, that it is not uncommon for initially asymptomatic exposures to become symptomatic over time. The symptoms are generally mild, ranging from spotting or leukorrhea to dyspareunia and/or vaginal pain. It is very common to try intravaginal estrogen although it is unclear if this has any true impact. Intervention is usually quite minimal with local excision under sedation. It can be performed in the office, especially with small defects and if there is capability of some sedation. It begins with identification of the exposed edges and an elliptical incision to incorporate the area. The exposed mesh is excised and the remaining edges are trimmed back under the vaginal margin. If the vaginal incision can be undermined, it will help in creating a good closure margin. It bears similarity to

the closure of a small vesicovaginal fistula. Repeat procedures are uncommon, unless suboptimal excision was performed in the initial procedure. When dyspareunia is seen in the face of mesh exposure, it typically resolves with successful closure.

The true etiology of mesh exposure is unclear and may vary. It appears to not be associated with any infectious etiology and there is rarely even mild evidence of local infection or inflammation. Reduced vascularity and biomechanical forces are more likely at fault. A minor exception to this description is cases where a mesh wing buttonholes the vagina during surgery and goes unnoticed. These are likewise easy to excise in the office and appear to have no consequence to the remainder of the repair.

The best prevention is strict adherence to the surgical technique guidelines with full-thickness incision, good tissue handling, no vaginal trimming, tension-free wound closure and keeping the mesh flat and tension free. The largest number of vaginal exposures is in the anterior incision line and they are generally less than 2 centimeters in largest dimension. Rarely are there cases where more mesh needs to be removed for reasons of exposure.

Dyspareunia and Vaginal Pain

As is the case in much of pelvic reconstructive surgery, the true rate of dyspareunia caused solely by the surgical procedure is difficult to assess. While preexisting dyspareunia due to POP resolves following surgery in the majority of cases, there are cases of new onset dyspareunia following GYNECARE PROLIFT System. In reviewing the early data, it may be as high as 6 - 9%. It may resolve with time or local treatment and intervention is required in only a small fraction of patients. As with other complications, it is likely to be related in part to experience and technique. Anecdotal reports of individual cases suggest that excessive tension during insertion may be a major causative factor. Other mistakes, such as performing plications, and trimming excess vaginal tissue may play an additional role. Surgeons need to explore the state of the patient's pelvic floor musculature before surgery. Preexisting pelvic floor dysfunction may help explain clusters of patients with fibromyalgia and pelvic pain who tend to develop postoperative dyspareunia. Younger patients seem to be more affected by dysparunia than elderly sexually active patients. This finding may be due to the patient's partners overall sexual function and decreasing penetration forces in elderly male patients when compared to younger male partners. There is an ongoing case series using validated sexual function instruments that may shed more objective light on this issue. The French have devoted much effort to looking at the nature of postoperative dyspareunia and its causes. There is an effort to create a classification system that would be useful to researchers and clinicians. Contraction of the mesh and/or reduction in the vaginal epithelial dimension is the primary exam finding in a subset of patients with dyspareunia.

In contrast, some patients have more levator spasm and local trigger points. This would be expected at the wing insertion site if it was pulled excessively and "bunches" into the muscular entry point. Similar pain is seen with obturator slings.

Vaginal pain occurring without provocation is more ominous but fortunately quite rare. The characteristic exam finding is the presence of palpable tenderness over the affected mesh site. The etiology is likely to be similar to the dyspareunia cases and prevention is based on the same principles. Treatment can include physical therapy with myofascial techniques. Local trigger point injection with local anesthetic and steroid or hypertonic saline has been successfully employed. Early postoperative injection of the steroid may be more effective than if delayed and full healing has occurred. Surgical intervention with excision of larger sections of mesh has also been utilized although the number of known cases is very small.

There are reports of self-limited rectal pain within the first month post-op that have resolved without intervention. In addition, some patients have developed inner thigh and groin pain that persisted longer than expected but resolved spontaneously within the first 8 - 10 weeks. The response may be hastened by referral to pain clinic or physical therapy techniques.

Defecatory dysfunction with or without tenesmus has also been noted. Exam is not particularly reliable for assigning causality since the posterior strap is often palpable transrectally after a GYNECARE PROLIFT System procedure in asymptomatic patients. The most important tool is prevention and defecatory dysfunction is not seen when the tension-free principles are adhered to. The rectal exam at the end of the procedure is the best assessment of this tension in the posterior compartment. If a relationship to an excessively tight posterior wing is determined, a midline mesh division, in effect lengthening the wings, could be considered. Surgeons are always concerned when dissecting tissue planes containing mesh but experience has shown that in experienced hands it is a reasonable procedure even if a larger excision is required. Ultrasound has been utilized to visualize displaced mesh in Europe but requires an understanding of the procedure and what to look for.

CLINICAL DATA Summary

Author	Patients	Follow-up	Exposure*	Success	Complications	
Cosson et al	90	12 mo	9 (10%) 5 (5.6%)	74 (81.6%)	Rectal injury Bleeding Fistula (VV)	1 2 1
Fatton et al	110	3 mo	5 (4.7%)	105 (95.3%)	Cystotomy Hematoma Retention	1 2 6
Murphy et al	89	5 mo	0 (0%)	84 (94.4%)	Cystotomy	2
Hinoul et al	29	6 mo	2 (6.9%)	28 (96.5%)	Cystotomy	1
Withagen et al	43	6 mo	2 (4.7%)	35 (81.4%)	Rectal injury Cystotomy Retention	1 2 1
Groenen et al[1]	26	2 mo	1 (3.8%)	26 (100%)	Retention	5
Perscheler et al[1]	80	N/A	8 (10%) 5 (6.25%)	N/A	Hematoma Cystotomy	2 2
Rivera et al[2]	82	3 mo	7 (11.7%)	N/A	Hematoma Bleeding	1 1
Total	549	6 mo	34 (6.2%) 12 (2.6%)	81.4-100%	Rectal injury Bleeding Retention Cystotomy	1.7% 1.3% 6.7% 1.7%

* second figure is exposures requiring intervention

[1] All abstracts 2006 IUGA : *Int Urogynecol J* 2006;17(s.2):S212(abstracts)
[2] All abstracts 2006 AUGS : *Int Urogynecol J* 2006;17(S.3):S460(abstracts)

Author	Patients	Follow-up	De Novo Sexual Limitaion
Murphy et al[1]	89	5 mo	2/38 (5.3%)
Fatton et al[2]	90	3 mo	3/35 (8.5%)

[1] Murphy et al. *Int Urogynecol J* 2006;17(s.2):S212(abstracts)
[2] Fatton et al. *Int Urogynecol J* 2006;17(s.2):S273(abstracts)

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APPENDIX

Gynecare PROLIFT*

Pelvic Floor Repair Systems

Surgical Technique

SURGICAL TECHNIQUE

Principles of the Procedure

The objective of the GYNECARE PROLIFT System procedure is to achieve a complete anatomic repair of pelvic floor defects in a standardized way. Depending on the site of the defect and surgeon's preference, the repair can either be anterior, posterior, or total. The repair is achieved by the placement of 1 or 2 synthetic non-absorbable polypropylene (GYNECARE GYNEMESH* PS) mesh implants via a vaginal approach.

The procedure requires a wide dissection in order to properly place the relatively large implants. These implants are designed to cover all existing or potential pelvic floor defects in a tension-free way.

Hysterectomy

Surgeon's preference and the patient's needs will determine if a concurrent hysterectomy is required. Peritonealization is recommended to avoid contact of the mesh to the bowel when a hysterectomy is performed. Retrospective data analysis suggests that the rate of mesh exposure may be higher when performing the TransVaginal Mesh (TVM) procedure with concurrent hysterectomy.

Vaginal Incisions

The principles regarding vaginal incisions include minimizing the size of the vaginal incisions and avoiding T-shaped incisions. Thus, when a vaginal hysterectomy is performed, it is recommended to avoid complementary sagittal incisions. This will dictate that the bladder dissection be performed through the pericervical incision.

Mesh Fixation

The implants are held in place by friction acting on the associated straps passing through tissue. If required, additional stitches may be used along with the straps to aid in proper placement of the implant. It is essential to install all of the available mesh straps to properly place and secure the implants.

Vaginal Preservation

It is recommended to avoid large vaginal excisions and fixation of the vagina to the implant.

Procedural Description

The procedure must be postponed if one of the following conditions is present:

- Vaginal infection
- Vaginal erosions
- Urinary infection

Additionally, the procedure should also be cancelled if a perioperative bladder or rectal injury occurs.

Preoperative Preparation

Repairs performed with the GYNECARE PROLIFT Pelvic Floor Repair System may be carried out under general or regional anesthesia according to surgeon's preference. Systematic preoperative antibiotic prophylaxis may be administered according to surgeon's preference.

The following steps are recommended prior to the start of the procedure:

- Antiseptic vaginal preparation
- Shaving or clipping of the pubic or hair
- Bowel preparation or preoperative enema
- Cleansing of the entire surgical area with appropriate antiseptic

The following steps are to be considered optional:

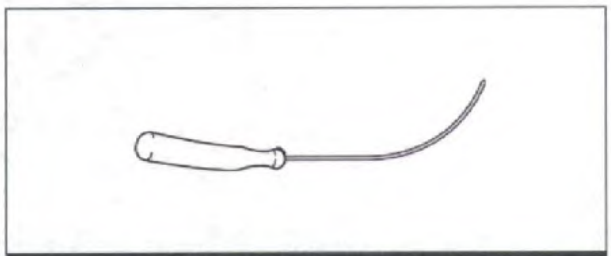
- Placement of an in-dwelling catheter after a urine culture has been performed
- Placement of lubricated packing in the rectum
- Infiltration of the vaginal wall by saline with a vasoconstrictive solution to ease dissection and reduce bleeding
- Administration of antibiotics

Patient Positioning

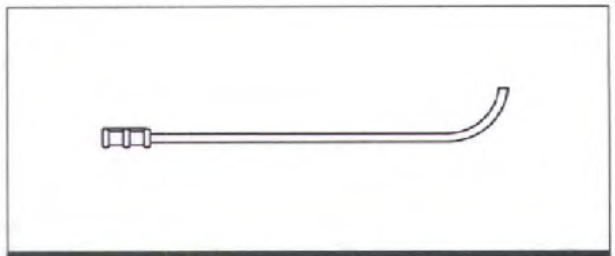
The patient should be placed in the lithotomy position with her buttocks slightly overlapping the table and her thighs flexed at approximately 90 degrees in relation to the plane of the table.

GYNECARE PROLIFT* System

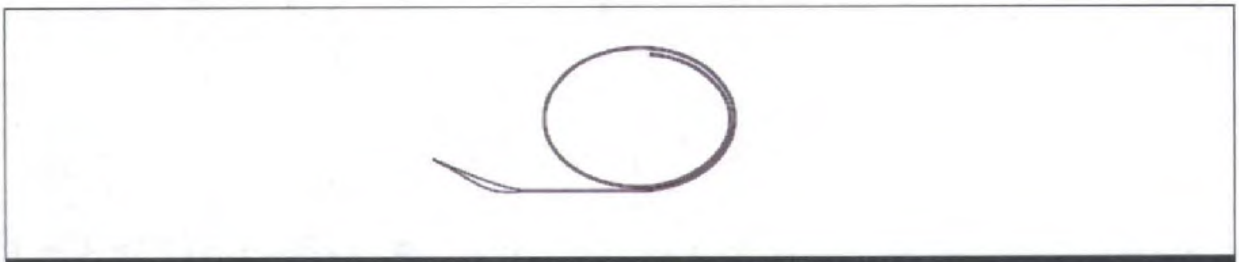
Nomenclature



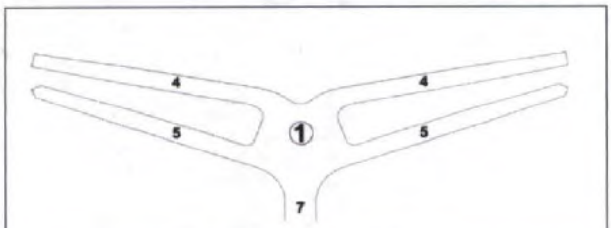
GYNECARE PROLIFT* Guide



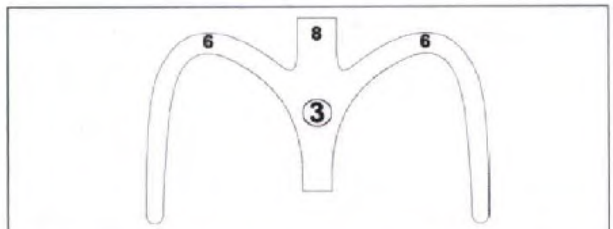
GYNECARE PROLIFT* Cannula



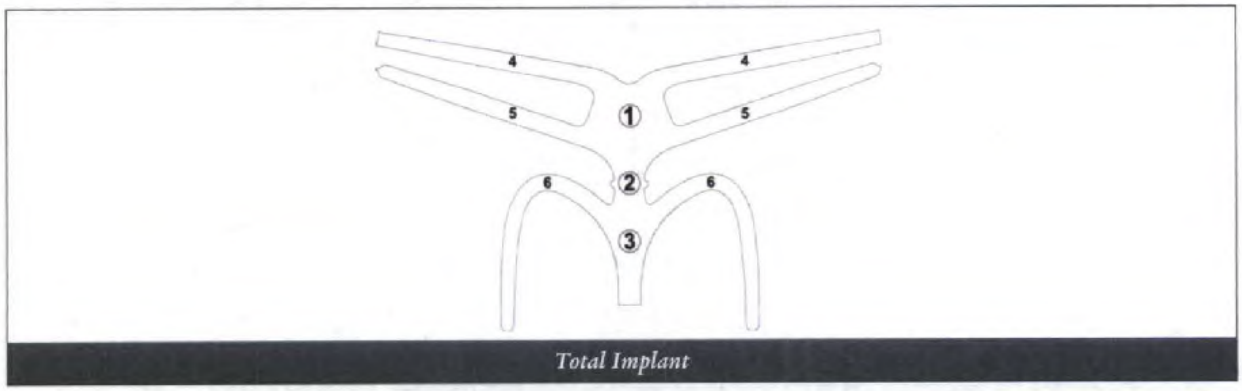
GYNECARE PROLIFT* Retrieval Device



Anterior Implant



Posterior Implant



Total Implant

3

TOTAL REPAIR with Vaginal Hysterectomy

The procedure begins with a vaginal hysterectomy with or without adnexectomy, followed by an anterior repair and then a posterior repair. Retrospective data analysis suggests that the rate of mesh exposure may be higher when performing the TVM procedure with concurrent hysterectomy.

Vaginal Incision and Hysterectomy

A standard vaginal hysterectomy is performed through a pericervical incision. It is recommended that users identify and retain the uterosacral ligaments or other elements of the cardinal ligament complex. These structures can later be interposed between the implant and the vagina or attached to the edges of the Total Implant according to surgeon's preference. Care must be taken to close the peritoneum.

The ensuing procedure steps will ideally be performed without any complementary sagittal incision whenever possible. Alternatively, a sagittal anterior colpotomy starting at the vaginal incision and ending approximately 1 cm from the bladder neck could be used if needed.

Anterior Dissection

Grasp and maintain control of the anterior vaginal wall with a series of 3 atraumatic forceps.

Perform a dissection of the entire thickness of the anterior vaginal wall. It is preferred to leave Halban's fascia (pubocervical fascia) on the vaginal wall. Dissection begins from the vaginal incision and should continue up to a point approximately 3-4 cm from the urinary meatus, in order to preserve and protect the region of the bladder neck.

Dissect the bladder laterally up to the vaginal cul de sac. When a defect exists, a finger will easily penetrate the paravesical fossa (paravaginal space). If no defect is evident, an orifice must be created in the fascia using blunt dissection techniques. This dissection is the starting point for a broad lateral dissection of the bladder, which will make it possible to identify the whole length of the arcus tendineus fascia pelvis (ATFP), which extends from the posterior aspect of the pubic arch to the ischial spine. If the ATFP cannot easily be identified, then palpation via a finger in the vagina from the pubic arch to the ischial spine should be used to ensure that straps 4 and 5 of the Anterior Segment (1) pass through at this level.

Anterior Segment (1) of Total Implant

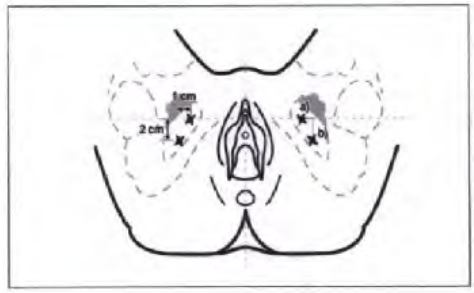
At this point, if required, plication of the bladder is performed in order to reduce the cystocele.

Preparation for Placement of the Anterior Segment

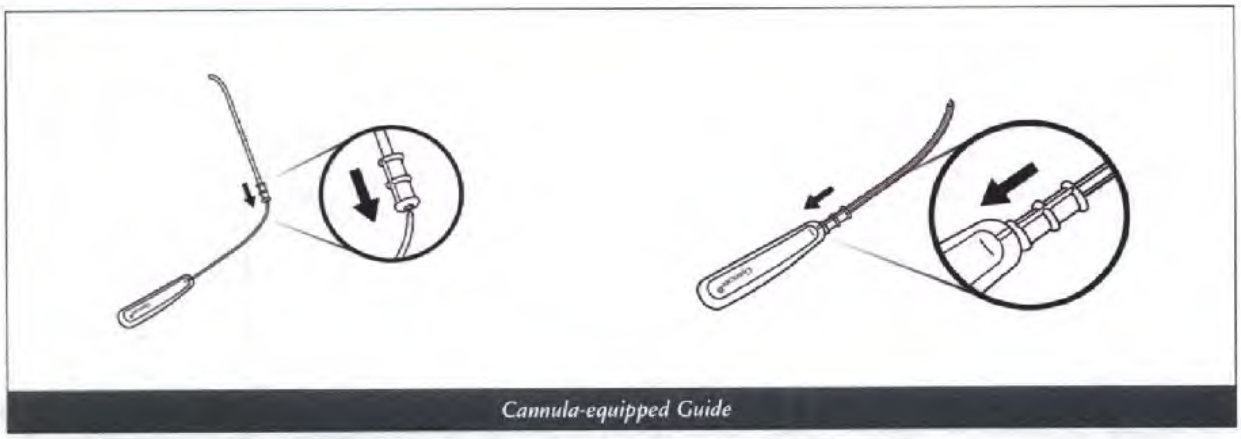
The following should be performed on the patient's left and right.

The Superficial Straps

The limits of the obturator foramen are identified by palpation between the thumb and index finger of the obturator membrane where it comes into contact with the bony boundaries. The cutaneous incision for passage of the superficial strap of the Anterior Segment (4) is made in the anteromedial edge of the obturator foramen, at the level of the urethral meatus. A 4-mm incision is made to enable the Guide with the Cannula installed to pass through the skin without tearing. It is helpful to mark the edge of the obturator foramen with a skin marking pen as a guide for the entrance locations.

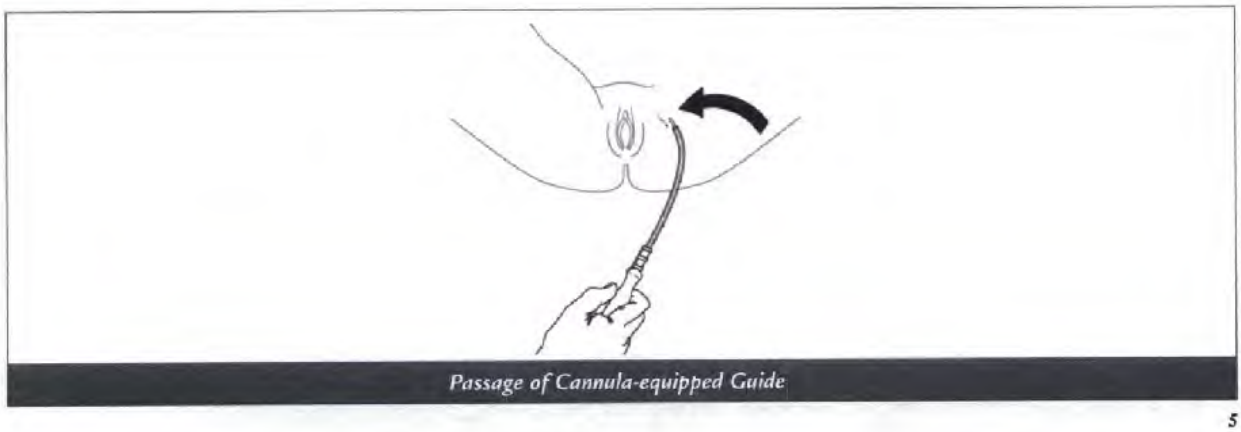


At the start of the passage, the Cannula-equipped Guide will perforate the obturator externus muscle and then the obturator membrane. The device should then be advanced medially through the obturator membrane and pass through the obturator internus muscle approximately 1 cm from the proximal (prepubic) end of the ATFP.

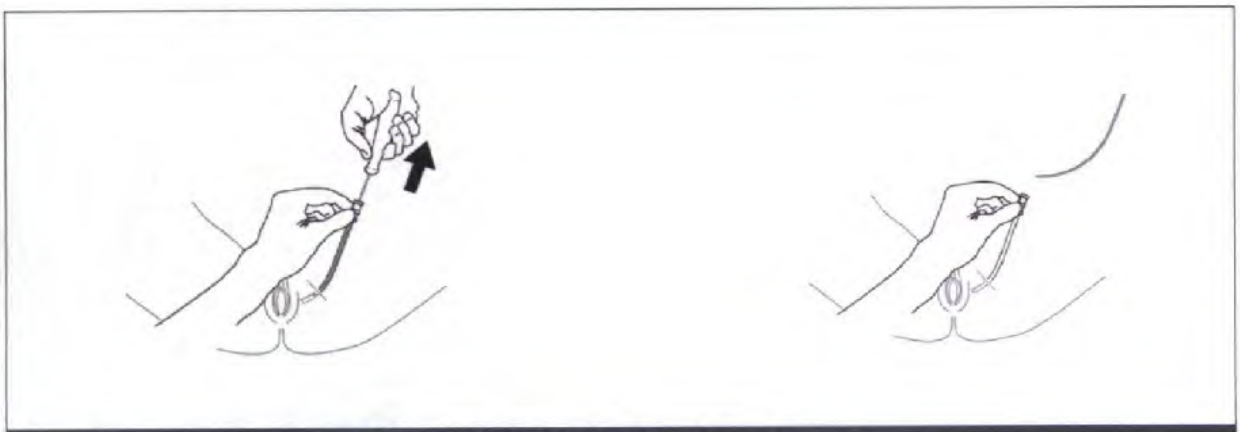


Cannula-equipped Guide

A finger positioned inside the vaginal dissection should always be used to ensure that the device follows the proper path and to provide protection to the bladder. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. Care should be taken to keep the Cannula in position, as the Guide is withdrawn to ensure that the tip of the Cannula remains slightly extended out of the tissue passage and the Cannula is not advanced further into the patient.



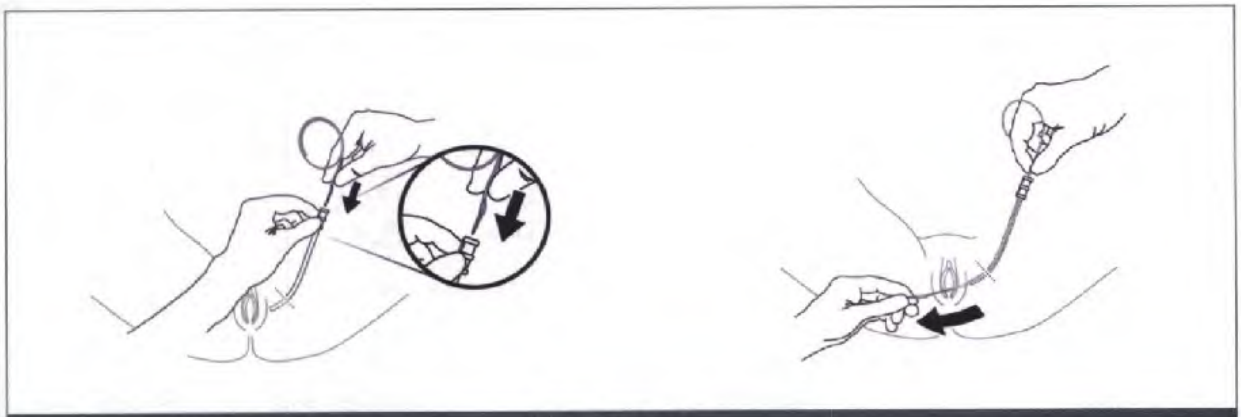
Passage of Cannula-equipped Guide



Remove Guide and leave Cannula

Once the Guide has been removed from the cannula, do not attempt to reinsert. Instead, remove the Cannula from the patient, reinstall the Guide, and then reinsert the Cannula into the patient.

Following placement of the Cannula, the Retrieval Device is passed down and advanced out of the distal end of the installed Cannula. The looped end of the Retrieval Device is then retrieved through the vaginal dissection and pulled out of the vagina with an instrument or a finger.

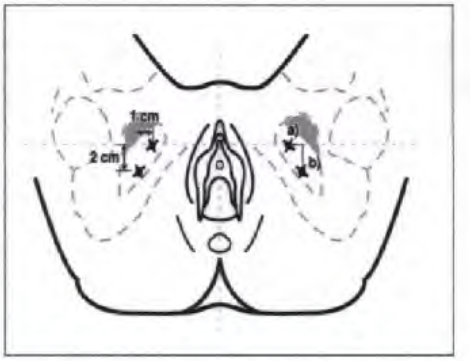


Pass Retrieval Device

The proximal end of the Retrieval Device can then be passed through the loop and secured to the drape or a retractor, thus reserving the Retrieval Device for later use in pulling the Total Implant strap into position. Optionally, the Cannulas may also be secured when placed in order to limit movement as the other Cannulas are installed. Care should be taken to avoid movement of the Cannulas following placement.

The Deep Straps

For placement of the deep strap of the Anterior Segment, a second cutaneous incision is made 1 cm lateral and 2 cm below the preceding incision at the posterolateral edge of the obturator foramen. To provide protection of the bladder, a Breisky or similar long retractor may be placed in the dissection. The Guide and Cannula are then inserted through the obturator externus muscle and then through the obturator membrane. The device should follow a downward trajectory once it passes through the obturator membrane. This movement will enable the Cannula-equipped Guide to emerge through the obturator internus muscle at the bottom of the paravesical fossa behind the ATFP, approximately 1 cm from the ischial spine.



A finger positioned inside the vaginal dissection should be used to ensure that the Guide follows the proper path and to provide protection to the bladder. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. The Retrieval Device is then installed and secured as described above.

Posterior Vaginal Incision

The recommended incision for this repair is a complementary sagittal colpotomy of the lower / distal half of the vagina ending at the vulva. Alternatively, the dissection can be performed through a complementary transverse incision made at the junction of the perineal skin and the vagina. If a perineal repair is indicated, a diamond-shaped incision overlapping the lower half of the sagittal colpotomy and the posterior perineum is recommended.

Posterior Dissection

Care should be taken when separating the rectum from the entire thickness of the vagina.

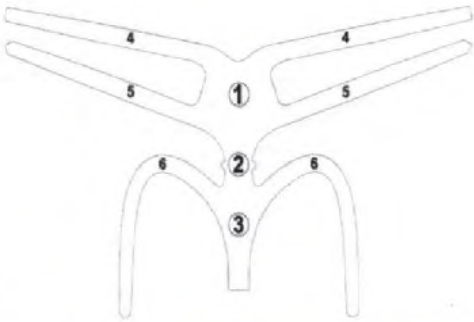
Dissection of the entire thickness of the posterior vaginal wall should be performed starting from the vaginal incision and continued up to the apex of the vagina. Laterally, the dissection opens the pararectal spaces and follows the space between the rectum and the levator ani muscle until the sacrospinous ligament can be palpated.

Generally, this dissection enables placement of a Breisky retractor or other such instrument which will be useful during later activities. Further deep dissection should then be performed to expose both sides of the sacrospinous ligament at the level of the ischial spine.

At this point, if required, a plication of the prerectal fascia in order to reduce the rectocele should be performed. Any required reductions of enteroceles should also be performed at this time.

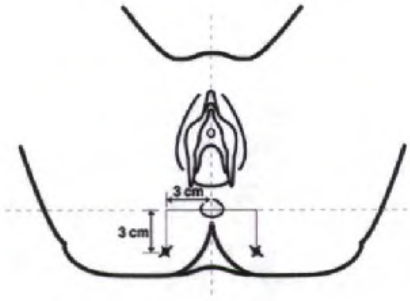
Preparation for Placement of the Posterior Segment

The following should be performed on the patient's left and right.



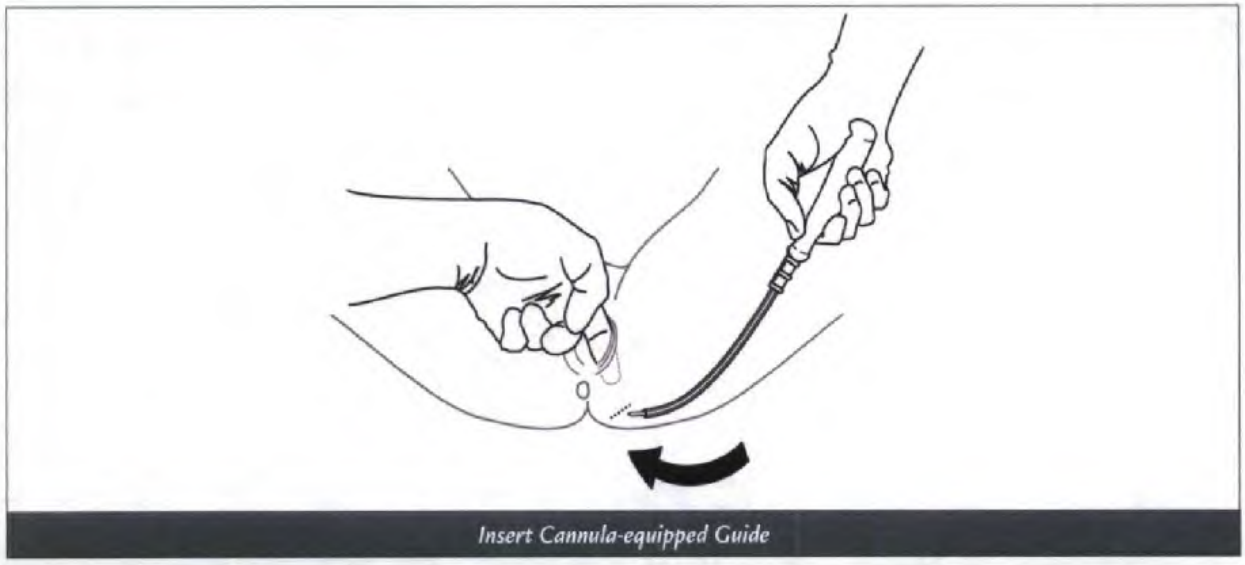
Posterior Segment (3) of Total Implant

The Posterior Segment (3) of the Total Implant is to be positioned in the ischioanal fossa, inferior to levator ani muscle, and secured by passage of the straps through the sacrospinous ligament and coccygeus muscles. To accomplish this, a 4 mm cutaneous incision is made approximately 3 cm lateral and 3 cm down from the anus.



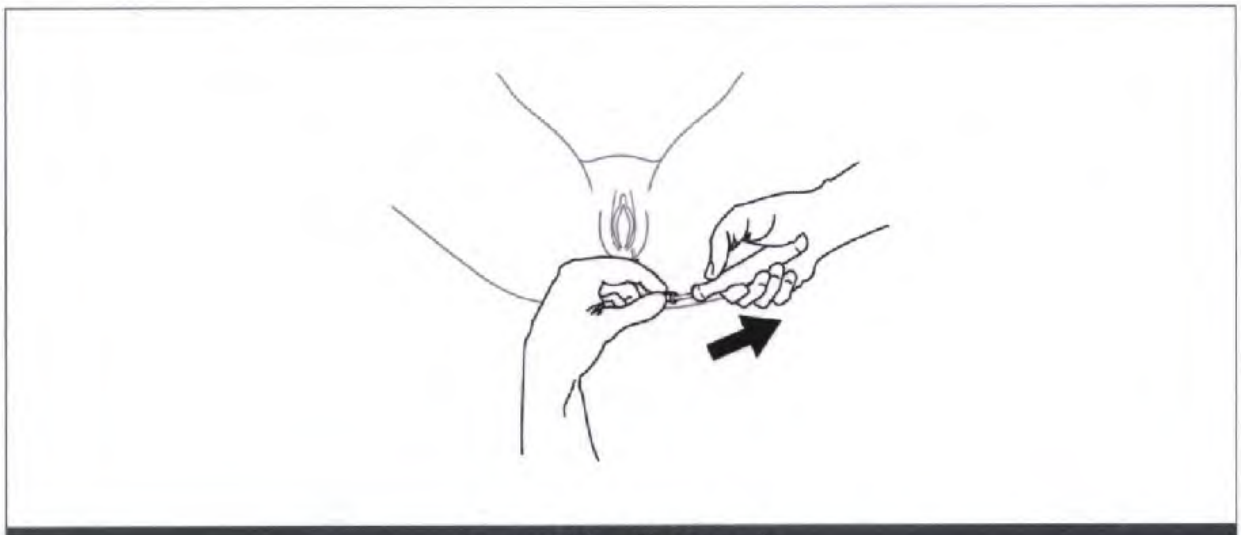
Posterior incision

The Cannula-equipped Guide is inserted into the incision, passed through the buttocks, and continued below the plane of the levator ani muscle, constantly controlled by the fingers within the vaginal dissection. The rectum should be pulled back and kept at a distance, either manually, or by using a retractor to prevent damage from the device.



Insert Cannula-equipped Guide

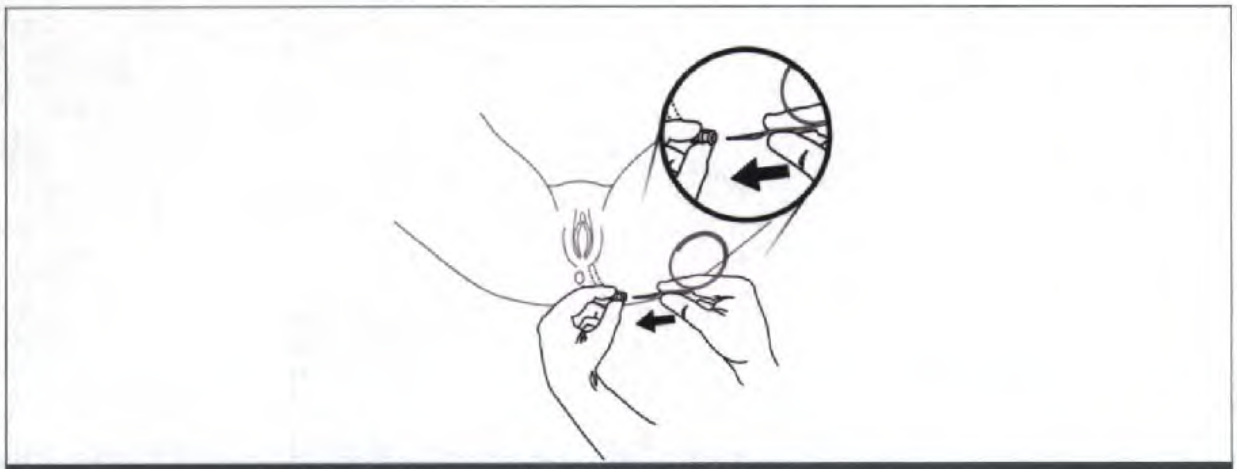
The Cannula-equipped Guide is advanced until it is in contact with the inferior side of the sacrospinous ligament approximately 3-4 cm medial to the ischial spine. It is then pushed through the sacrospinous ligament under digital control, thus exposing the tip of the Guide and Cannula. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. Care should be taken to keep the Cannula in position as the Guide is withdrawn to ensure that the tip of the Cannula remains extended out of the tissue passage and the Cannula is not advanced further into the patient.



Remove Guide and leave Cannula

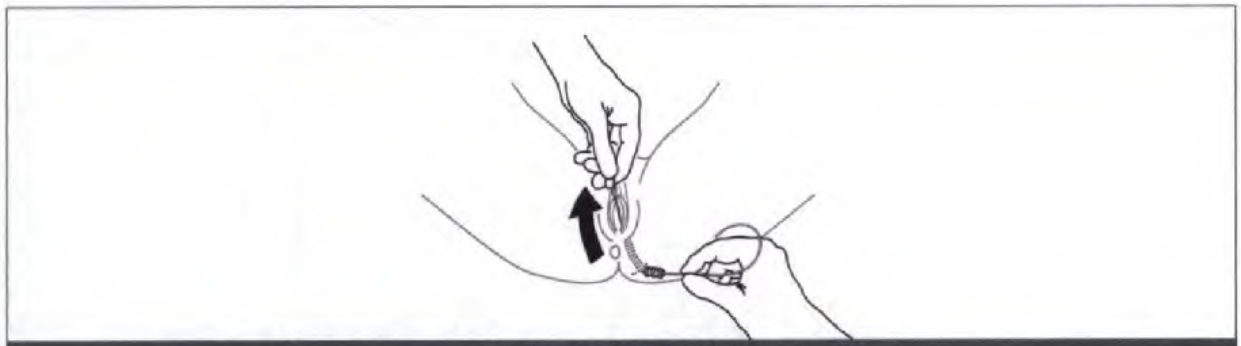
Once the Guide has been removed from the cannula, do not attempt to reinsert. Instead, remove the Cannula from the patient, reinstall the Guide, and then reinsert the Cannula into the patient.

Following placement of the Cannula, the Retrieval Device is passed down and advanced out of the distal end of the Cannula.



Pass Retrieval Device

The looped end of the Retrieval Device is then retrieved through the vaginal dissection and pulled out of the vagina with an instrument or a finger.



Retrieve the Retrieval Device

The proximal end of the Retrieval Device can then be passed through the loop and secured to the drape or a retractor with a hemostat, thus reserving the Retrieval Device for later use in pulling the Total Implant strap into position. Optionally, the Cannulas may also be secured when placed in order to limit movement as the other Cannulas are installed. Care should be taken to avoid movement of the Cannulas following placement.

An alternative approach is to directly fixate the Posterior Segment straps (6) to the superficial aspect of the sacrospinous ligament. This can be accomplished by trimming the distal portion of these straps to the proper length and performing fixation with suture or alternative fixation means.

Straps (6) of Posterior Segment

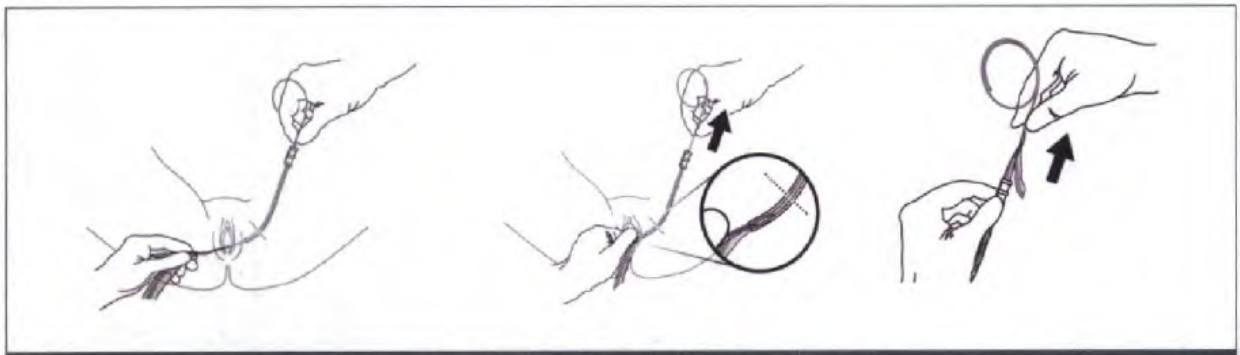
Placement of the Total Implant

Anterior Segment Placement

Placement of the Total Implant starts anteriorly. The distal ends of the Total Implant straps are sequentially captured in the loops at the end of the Retrieval Devices.

Capture distal ends

The loops are then pulled through the Cannulas to the proximal exit. The ends of the straps of the Anterior Segment are uniquely shaped with the superficial straps having squared ends and the deep straps having triangular ends.



Pull loops through Cannula

Optimally, the Anterior Segment of the Total Implant will be positioned tension-free under the bladder while ensuring lateral contact against the ATFP. Lateral contact of the Total Implant to the ATFP should be carefully verified.

If required, small reductions in the dimensions of the Total Implant to ensure proper fit should be performed at this point.

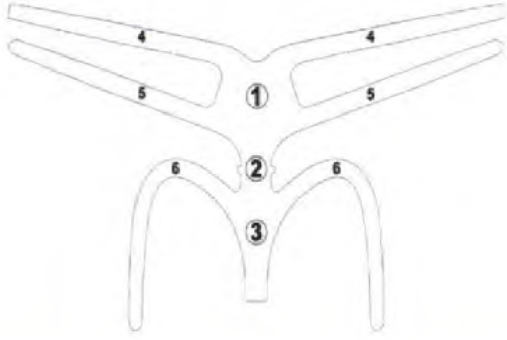
Further fine adjustment of the tension and position of the Total Implant may be performed following closure of the vaginal incisions at the end of the procedure.

Fixing the Total Implant at each of the pubic insertions of the puborectalis muscle with sutures is optional. If the surgeon elects to do this, it is essential that the anterior notch of the Total Implant leaves the neck of the bladder largely free. Additional fixations remain optional.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh, it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

Middle Segment Placement

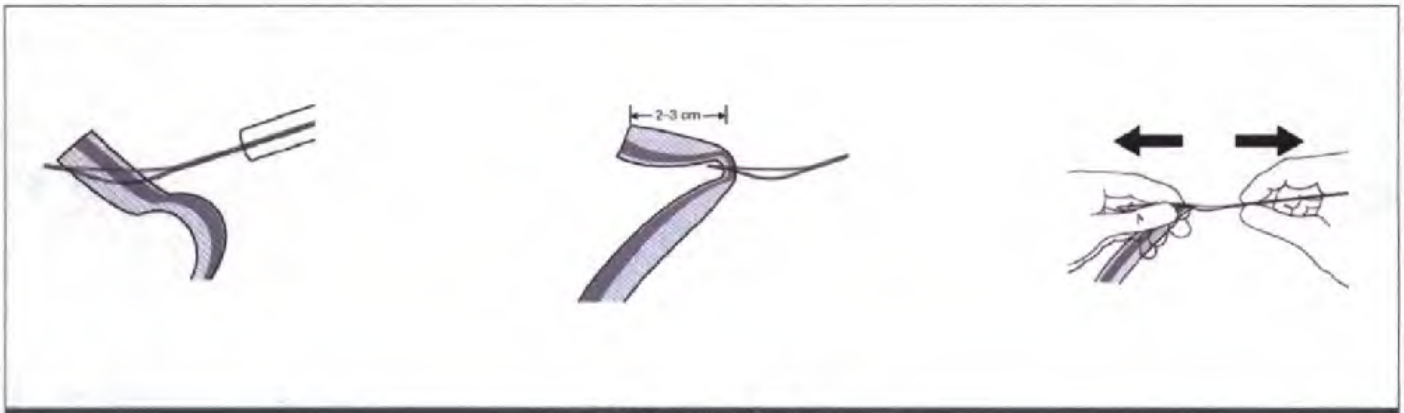
The Middle Segment (2) of the Total Implant should be positioned in the posterior dissection behind the vaginal apex. The uterosacral ligaments or other elements of the cardinal ligament complex can be either interposed between the Total Implant and the vagina or attached to the edges of the Total Implant according to surgeon's preference.



Middle Segment (2) of Total Implant

Posterior Segment Placement

Installation of the Posterior Segment of the Total Implant requires the distal ends of the straps to be sequentially captured in the loops at the end of the Retrieval Devices.

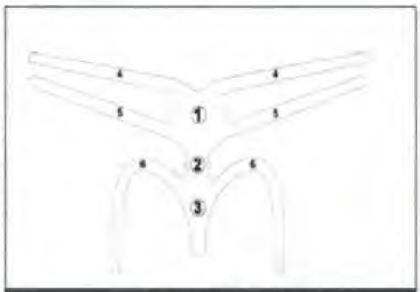


Capture distal ends

The loops are then pulled through the Cannulas to the proximal exit. The Posterior Segment can be positioned once both straps have been retrieved.

Optimally, the Posterior Segment of the Total Implant will be positioned tension-free above the rectum with its lateral edges against the superior surface of the levator ani muscles. Minor reductions in Total Implant length should be made at this point, if required, to ensure proper fit. If desired, sutures may be used bilaterally on the levator ani muscles at the external edge of the Total Implant to ensure aid in positioning.

Further fine adjustment of the tension and position of the Total Implant may be performed following closure of the vaginal incisions at the end of the procedure.



Straps (6) of Posterior Segment

An alternative approach to fixation of the Posterior Segment is to directly fixate the straps (6) to the superficial aspect of the sacrospinous ligament. This can be accomplished by trimming the distal portion of the straps (6) to the proper length and fixating with suture or other alternative means.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh, it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

Vaginal Closure and Final Adjustment

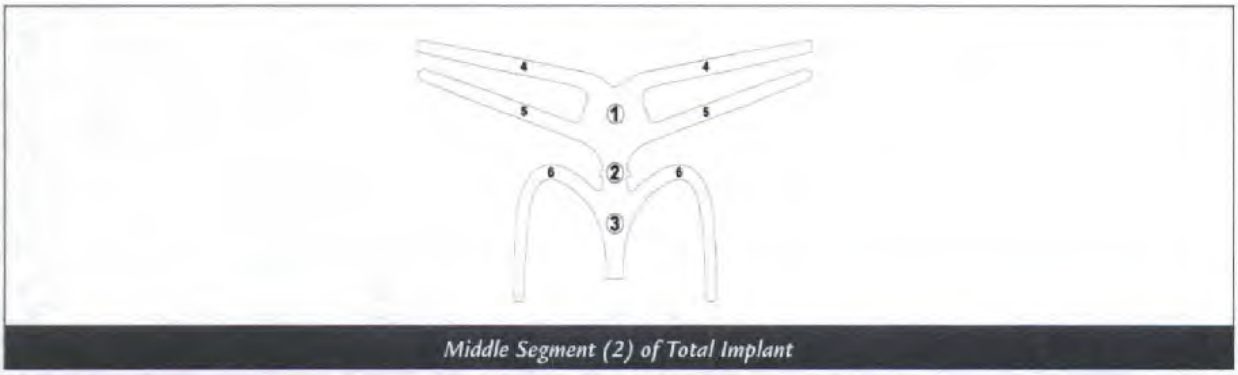
Closure of the vaginal incisions can be made according to surgeon's preference. The straps should be used to make any required additional fine adjustment to the Total Implant position, taking care to not place the mesh under tension. The Cannulas can be withdrawn once the Total Implant is properly positioned. The ends of the Total Implant straps extending out of the cutaneous incisions should be trimmed at the level of the dermis. These incisions are closed according to surgeon's preference.

TOTAL REPAIR with Uterine Preservation

Surgeon's preference and the patient's needs will determine if a concurrent hysterectomy is required. If the uterus is maintained, the following information includes important differences of the procedure previously described.

Implant Preparation

The Total Implant must be cut at the midpoint of the Middle Segment (2).



Middle Segment (2) of Total Implant

Anterior Vaginal Incision

The recommended incision for this repair is a sagittal colpotomy starting 1 cm below the cervix and ending approximately 1 cm from the bladder neck. Alternatively, a transverse incision could be used.

Anterior Mesh Fixation

The posterior part of the Anterior Segment should be attached to the anterior face of the uterine isthmus about 2 cm above the cervix with a single stitch of PROLENE Suture.

Posterior Vaginal Incision

The recommended incision for this repair is a sagittal colpotomy of the lower half of the vagina ending at the vulva. Alternatively, the dissection could be performed through a transverse incision of the perineum made at the junction of the perineal skin and the vagina. If a perineal repair is indicated, a diamond-shaped incision overlapping the lower half of the sagittal colpotomy and the posterior perineum is recommended.

Posterior Mesh Fixation

The anterior portion of the Posterior Segment is attached to the posterior face of the uterine isthmus about 2 cm above the cervix with a single stitch of PROLENE Suture.

TOTAL REPAIR in Case of Previous Hysterectomy

The following details important differences associated with women who have had a prior hysterectomy.

Vaginal Incision

The recommended incision for this repair is a sagittal colpotomy starting about 1 cm above the vaginal scar and ending approximately 1 cm from the bladder neck. Alternatively, a transverse incision could be used.

Mesh Fixation

Generally, there is no structure that can readily be identified for attachment to the central region of the implant. If the uterosacral ligaments exist, they can be used in the same way as previously described.

TOTAL REPAIR in the Absence of a Posterior Defect (Anterior / Apical Repair)

When the patient presents the association of a cystocele and a hysterocele or a vaginal vault prolapse but no significant posterior defect (rectocele), the GYNECARE PROLIFT Total Pelvic Floor Repair System may also be used to perform a combination anterior/apical repair.

This repair is accomplished by the following:

- Performing the required anterior and posterior incisions and dissection
- Removing the unneeded lower part of the Posterior Segment of the Total Implant (straps must be left intact)
- Placing the Anterior Segment per standard procedures
- Placing and fixing the Middle Segment per standard procedures
- Securing the straps of the abbreviated Posterior Segment to or through the sacrospinous ligament as previously described

The suspension of the uterus (in case of uterine preservation) or the vaginal vault (in case of concomitant or previous hysterectomy) relies on the Posterior Segment of the Total Implant.

In case of uterine conservation, the anterior part of the Posterior Segment of the Total Implant is attached to the posterior face of the uterine isthmus about 2 cm above the cervix with a single stitch of non absorbable monofilament suture.

ANTERIOR REPAIR with Hysterectomy

Vaginal Incision and Hysterectomy

A standard vaginal hysterectomy is performed through a pericervical incision. It is recommended that users identify and retain the uterosacral ligaments or other elements of the cardinal ligament complex. These structures can later be interposed between the Anterior Implant and the vagina or attached to the edges of the Anterior Implant according to surgeon's preference. Care must be taken to close the peritoneum.

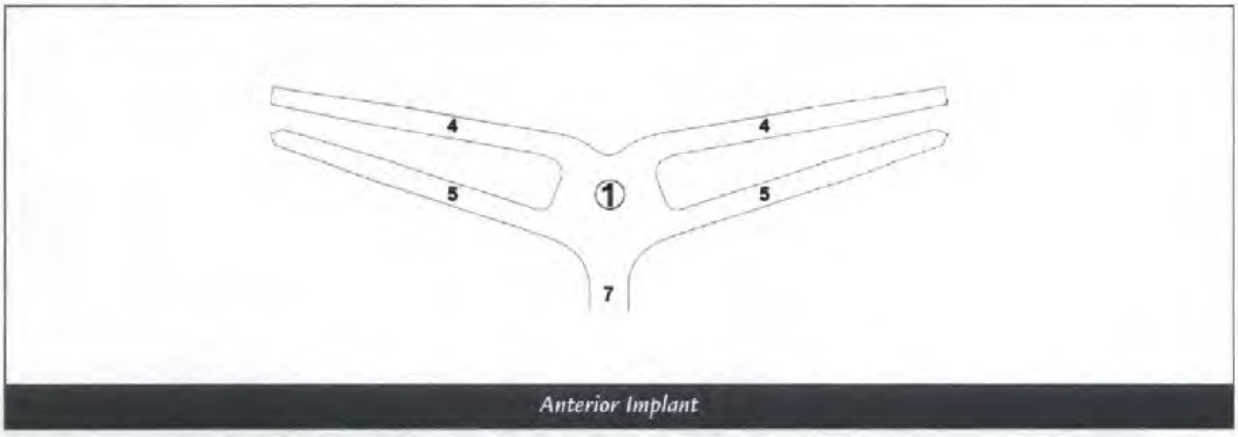
The next steps will ideally be performed without any complementary sagittal incision whenever possible. Alternatively, a sagittal anterior colpotomy starting at the vaginal incision and ending approximately 1 cm from the bladder neck could be used if needed.

Anterior Dissection

Grasp and maintain control of the anterior vaginal wall with a series of 3 atraumatic forceps.

Perform a dissection of the entire thickness of the anterior vaginal wall. It is preferred to leave Halban's fascia (pubocervical fascia) on the vaginal wall. Dissection begins from the vaginal incision and should continue up to a point approximately 3-4 cm from the urinary meatus, in order to preserve and protect the region of the bladder neck.

Dissect the bladder laterally up to the vaginal cul de sac. When a defect exists, a finger will easily penetrate the paravesical fossa (paravaginal space). If no defect is evident, an orifice must be created in the fascia using blunt dissection techniques. This dissection is the starting point for a broad lateral dissection of the bladder, which will make it possible to identify the whole length of the arcus tendineus fascia pelvis (ATFP), which extends from the posterior aspect of the pubic arch to the ischial spine. If the ATFP cannot easily be identified, then palpation via a finger in the vagina from the pubic arch to the ischial spine should be used to ensure that straps 4 and 5 of the Anterior Implant pass through at this level.



Anterior Implant

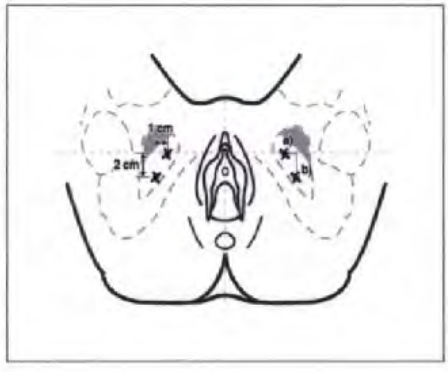
At this point, if required, plication of the bladder is performed in order to reduce the cystocele.

Preparation for Placement of the Anterior Implant

The following should be performed on the patient's left and right.

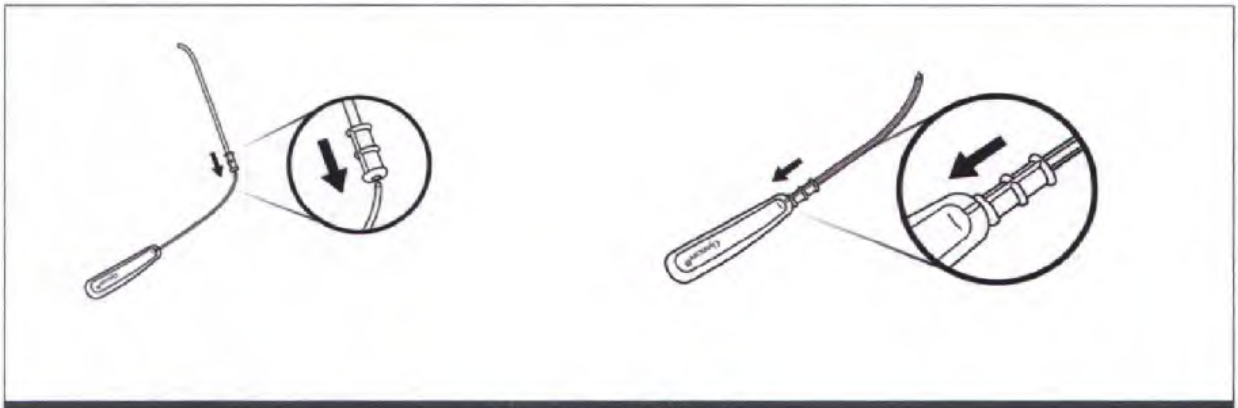
The Superficial Straps

The limits of the obturator foramen are identified by palpation between the thumb and index finger of the obturator membrane where it comes into contact with the bony boundaries.



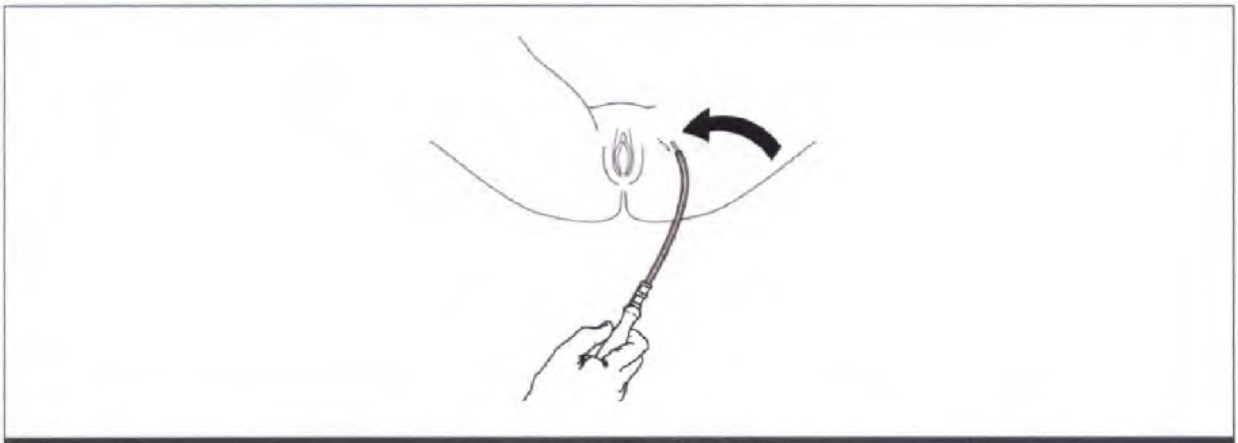
The cutaneous incision for passage of the superficial strap (4) of the Anterior Implant is made in the anteromedial edge of the obturator foramen, at the level of the urethral meatus. A 4 mm incision is made to enable the Guide with the Cannula installed to pass through the skin without tearing. It is helpful to mark the edge of the obturator foramen with a skin marking pen as a guide for the entrance locations.

At the start of the passage, the Cannula-equipped Guide will perforate the obturator externus muscle and then the obturator membrane. The device should then be advanced medially through the obturator membrane and pass through the obturator internus muscle approximately 1 cm from the proximal (prepubic) end of the ATFP.

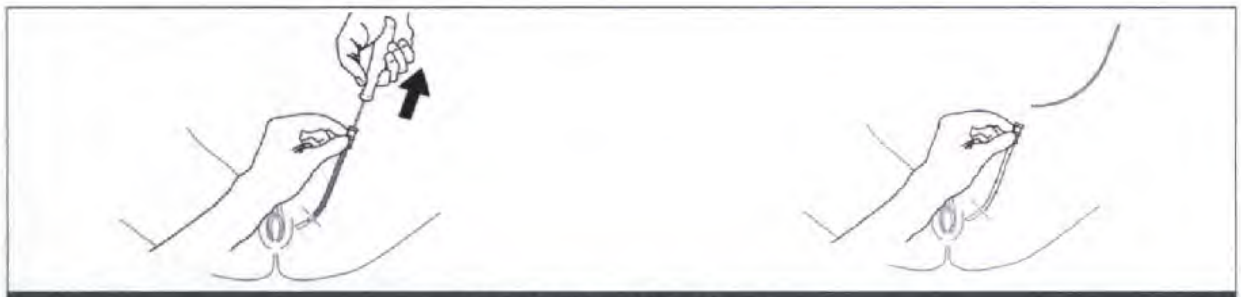


Cannula-equipped Guide

A finger positioned inside the vaginal dissection should always be used to ensure that the device follows the proper path and to provide protection to the bladder. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. Care should be taken to keep the Cannula in position as the Guide is withdrawn to ensure that the tip of the Cannula remains slightly extended out of the tissue passage and the Cannula is not advanced further into the patient.



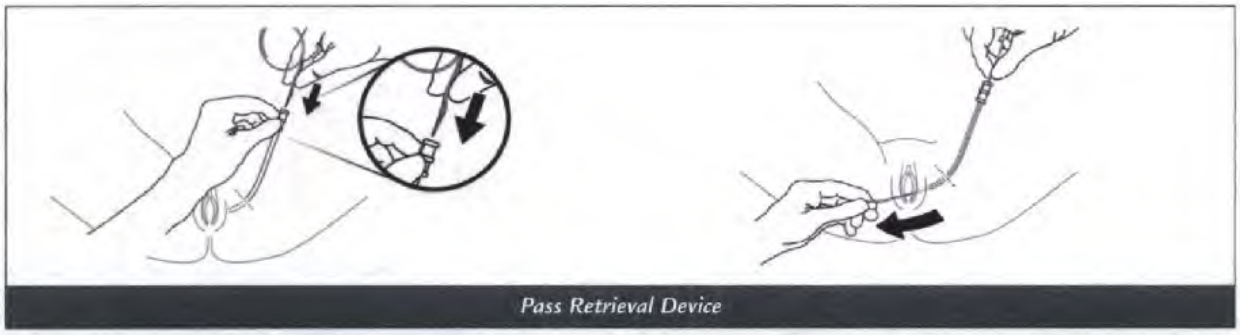
Passage of Cannula-equipped Guide



Remove Guide and leave Cannula

Once the Guide has been removed from the cannula, do not attempt to reinsert. Instead, remove the Cannula from the patient, reinstall the Guide, and then reinsert the Cannula into the patient.

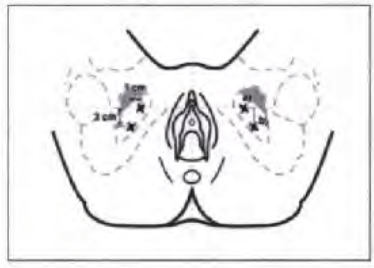
Following placement of the Cannula, the Retrieval Device is passed down and advanced out of the distal end of the installed Cannula. The looped end of the Retrieval Device is then retrieved through the vaginal dissection and pulled out of the vagina with an instrument or a finger.



Pass Retrieval Device

The proximal end of the Retrieval Device can then be passed through the loop and secured to the drape or a retractor, thus reserving the Retrieval Device for later use in pulling the Implant strap into position. Optionally, the Cannulas may also be secured when placed in order to limit movement as the other Cannulas are installed. Care should be taken to avoid movement of the Cannulas following placement.

The Deep Straps

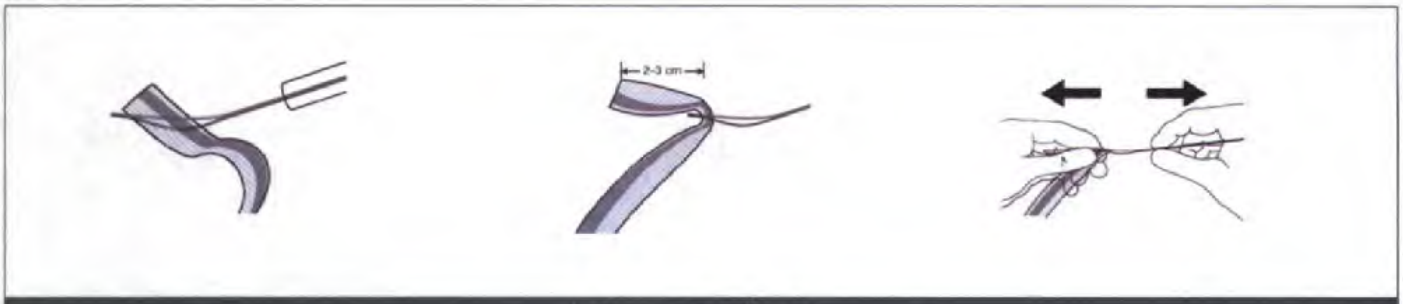


For placement of the deep strap (5) of the Anterior Implant, a second cutaneous incision is made 1 cm lateral and 2 cm below the preceding incision at the posterolateral edge of the obturator foramen. To provide protection of the bladder, a Breisky or similar long retractor may be placed in the dissection. The Guide and Cannula are then inserted through the obturator externus muscle and then through the obturator membrane. The device should follow a downward trajectory once it passes through the obturator membrane. This movement will enable the Cannula-equipped Guide to emerge through the obturator internus muscle at the bottom of the paravesical fossa behind the ATFP, approximately 1 cm from the ischial spine.

A finger positioned inside the vaginal dissection should be used to ensure that the Guide follows the proper path and to provide protection to the bladder. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. The Retrieval Device is then installed and secured as described above.

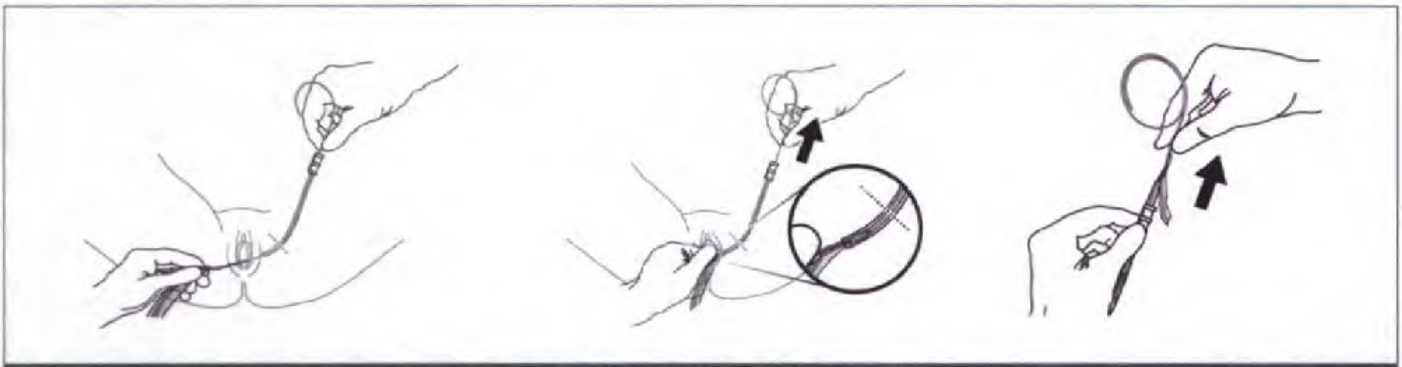
Placement of the Anterior Implant

The distal ends of the Anterior Implant straps are sequentially captured in the loops at the end of the Retrieval Devices.



Capture distal ends

The loops are then pulled through the Cannulas to the proximal exit. The ends of the straps of the Anterior Implant are uniquely shaped with the superficial straps having squared ends and the deep straps having triangular ends.



Pull loops through Cannula

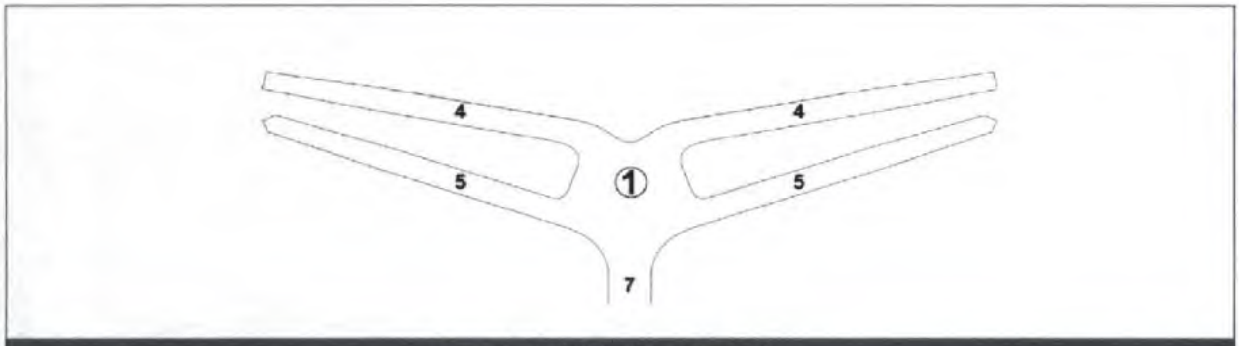
The Anterior Implant can be carefully positioned once all straps have been retrieved. Optimally, the Anterior Implant will be positioned tension-free under the bladder while ensuring lateral contact against the ATFP. Lateral contact of the Anterior Implant to the ATFP should be carefully verified. If required, small reductions in the dimensions of the Anterior Implant to ensure proper fit should be performed at this point.

Further fine adjustment of the tension and position of the Anterior Implant may be performed following closure of the vaginal incisions at the end of the procedure.

Fixing the Anterior Implant at each of the pubic insertions of the puborectalis muscle with sutures is optional. If the surgeon elects to do this, it is essential that the anterior notch of the Anterior Implant leaves the neck of the bladder largely free.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

The Posterior Tail (7) of the Anterior Implant can be left free, positioned under the inferior margin of the bladder, or attached to the parametrial / cardinal or uterosacral ligaments according to the surgeon's preference. Additional fixations remain optional.



Posterior Tail (7) of Anterior Implant

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

Vaginal Closure and Final Adjustment

Closure of the vaginal incisions can be made according to surgeon's preference. The straps should be used to make any required additional fine adjustment to implant position, taking care to not place the mesh under tension. Following proper positioning, the Cannulas can be carefully withdrawn.

The ends of the Anterior Implant straps extending out of the cutaneous incisions of the obturator foramen should be trimmed at the level of the dermis. These incisions are then closed according to surgeon's preference.

ANTERIOR REPAIR with Uterine Preservation

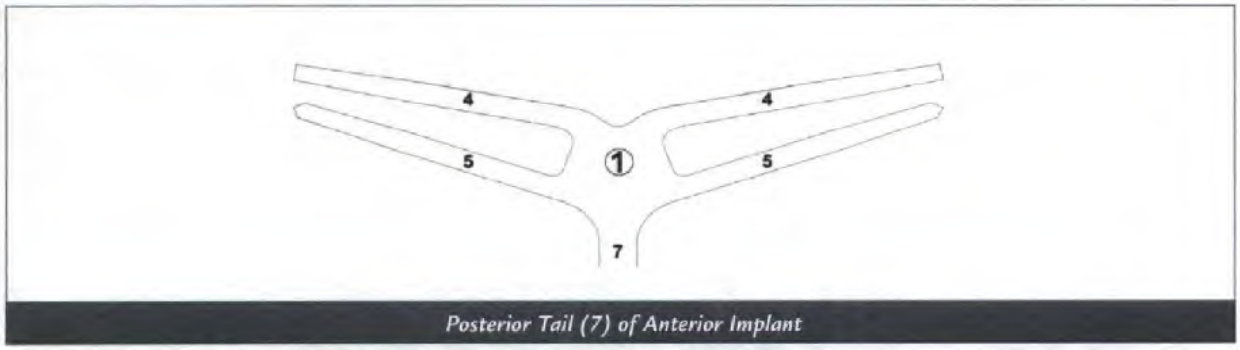
The following includes important differences associated with the procedure when the uterus is preserved:

Anterior Vaginal Incision

The recommended incision for this repair is a sagittal colpotomy starting 1 cm below the cervix and ending approximately 1 cm from the bladder neck. Alternatively, a transversal incision could be used.

Anterior Mesh Fixation

The Posterior Tail (7) of the Anterior Implant is attached to the anterior face of the uterine isthmus about 2 cm above the cervix with a single stitch of PROLENE Suture.



Posterior Tail (7) of Anterior Implant

POSTERIOR REPAIR with Hysterectomy

Vaginal Incision and Vaginal Hysterectomy

A standard vaginal hysterectomy is performed through a pericervical incision. It is recommended that users identify and retain the uterosacral ligaments or other elements of the cardinal ligament complex. These structures can later either be interposed between the Posterior Implant and the vagina or attached to the edges of the Posterior Implant according to surgeon's preference. Care must be taken to close the peritoneum.

Posterior Vaginal Incision

The recommended incision for this repair is a complementary sagittal colpotomy of the lower / distal half of the vagina ending at the vulva. Alternatively, the dissection can be performed through a complementary transverse incision made at the junction of the perineal skin and the vagina. If a perineal repair is indicated, a diamond-shaped incision overlapping the lower half of the sagittal colpotomy and the posterior perineum is recommended.

Posterior Dissection

Care should be taken to accomplish separation of the rectum from the entire thickness of the vagina. Perform a dissection of the entire thickness of the posterior vaginal wall. Dissection starts from the vaginal incision and should be continued up to the apex of the vagina. Laterally, the dissection opens the pararectal spaces and follows the space between the rectum and the levator ani muscle until the sacrospinous ligament can be palpated. Generally, this dissection allows placement of a tool such as a Breisky retractor or other such instrument which will be useful during later activities. Further deep dissection should then be performed on both sides to expose or palpate the distal part of the sacrospinous ligament at the level of the ischial spine.

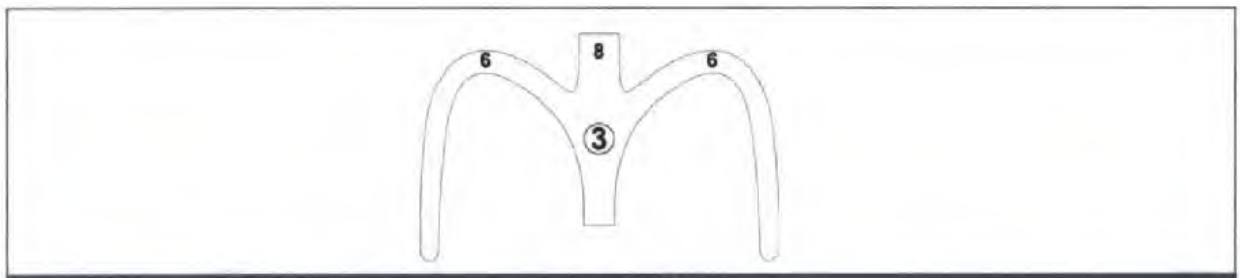
At this point, if required, a plication of the prerectal fascia in order to reduce the rectocele should be performed. Any required reductions of enteroceles should also be done at this time.

Preparation for Placement of the Posterior Implant

Two approaches for fixating the Posterior Implant are suggested.

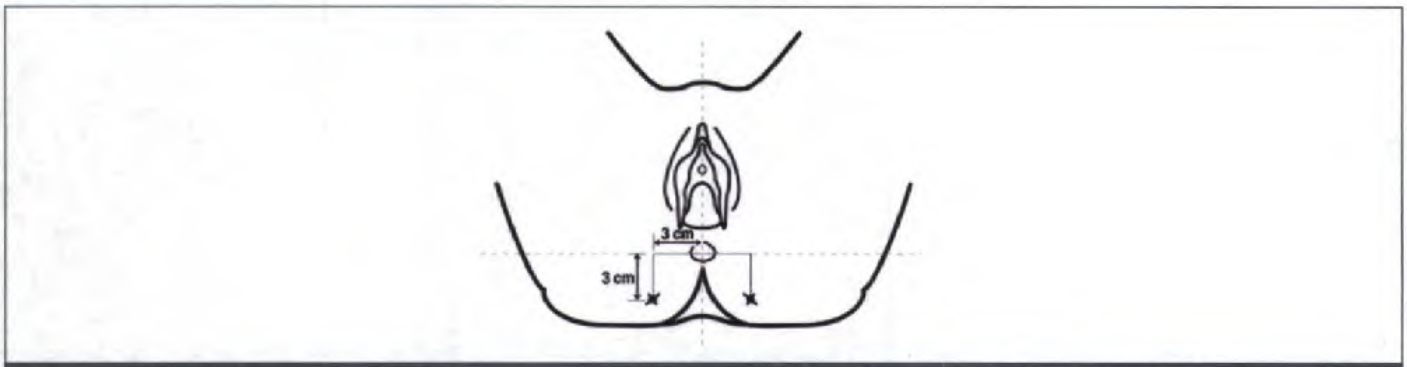
Transgluteal Fixation

The straps of the Posterior Implant are passed transgluteally and secured by passage of the straps through the sacrospinous ligament and coccygeus muscle.



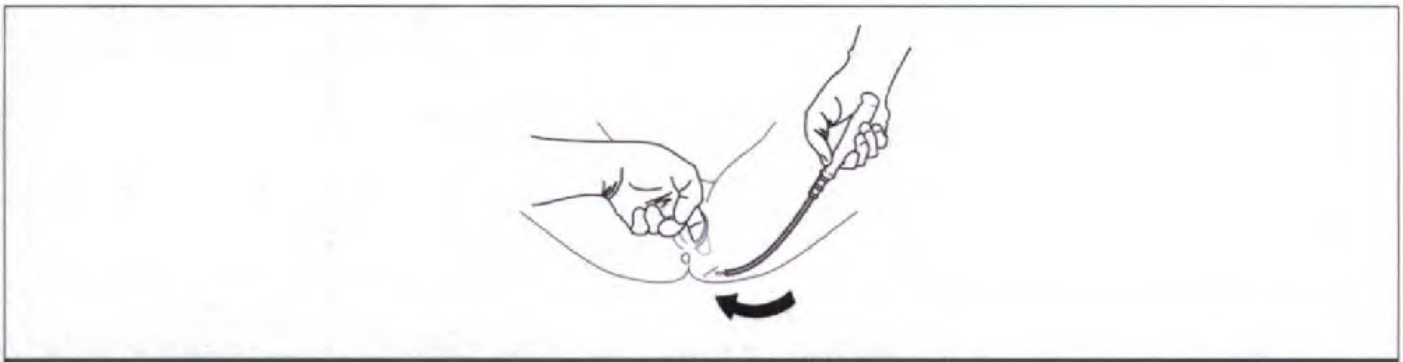
Posterior Implant

To accomplish this, a 4-mm cutaneous incision is made approximately 3 cm lateral and 3 cm down from the anus. If desired, sterile packing coated with lubricant may be inserted into the rectum first to ensure better appreciation of the position of the rectal ampulla.



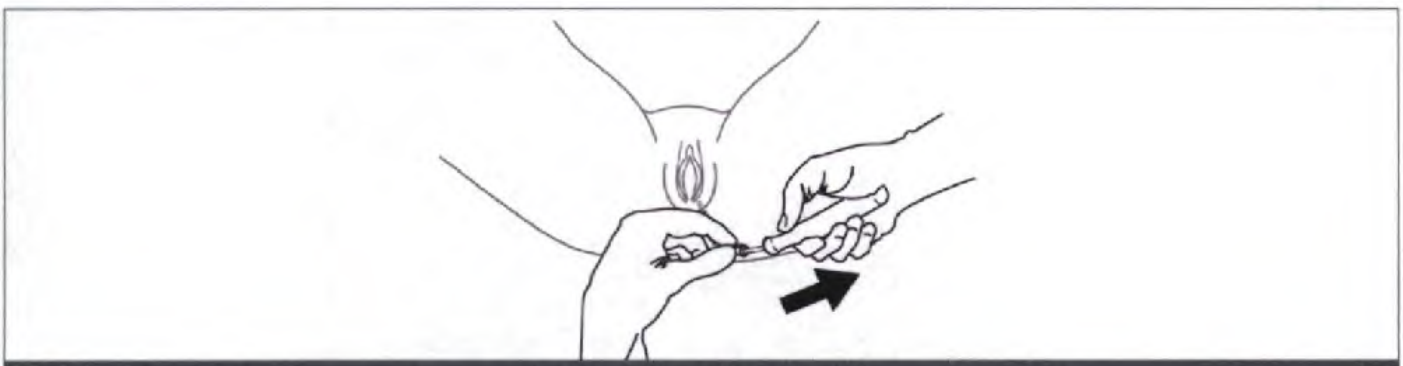
Posterior Incision

The Cannula-equipped Guide is inserted into the incision, passed through the buttocks, and continued below the plane of the levator ani muscle, constantly controlled by the fingers within the vaginal dissection. The rectum should be pulled back and kept at a distance, either manually, or by using a retractor to prevent damage from the device.



Insert Cannula-equipped Guide

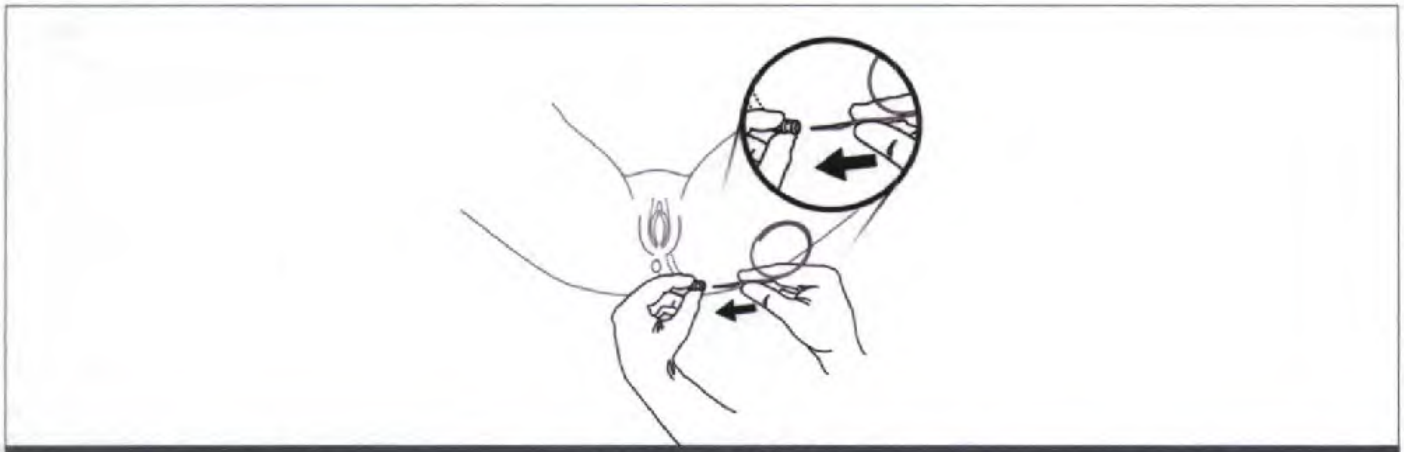
The device is advanced until it is in contact with the inferior side of the sacrospinous ligament approximately 3-4 cm medial to the ischial spine. The device is pushed through the sacrospinous ligament under digital control, thus exposing the tip of the Guide and Cannula. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. Care should be taken to keep the Cannula in position as the Guide is withdrawn to ensure that the tip of the Cannula remains extended out of the tissue passage and the Cannula is not advanced further into the patient.



Remove Guide and leave Cannulla

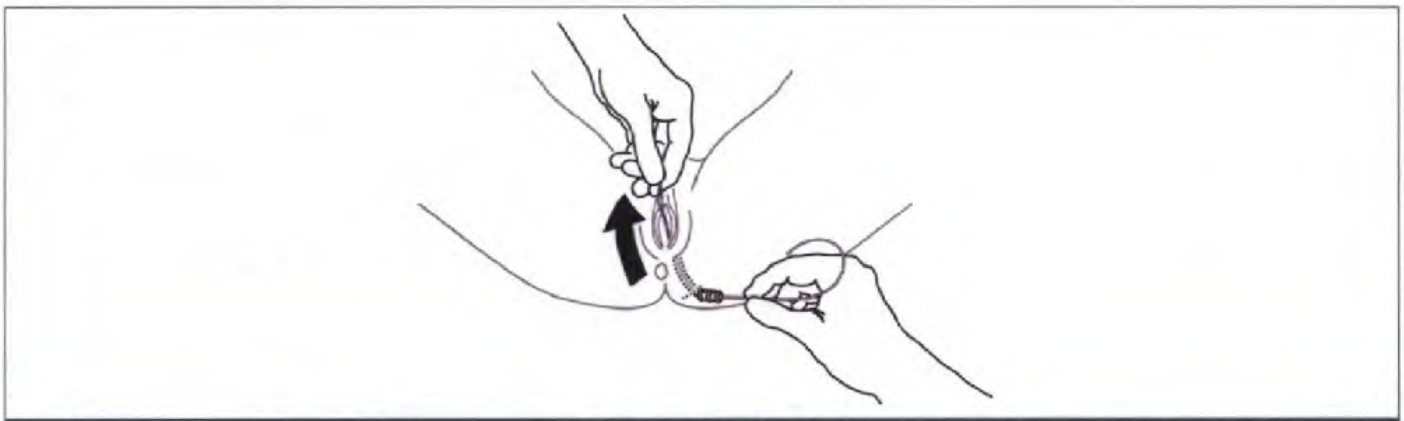
Once the Guide has been removed from the cannula, do not attempt to reinsert. Instead, remove the Cannula from the patient, reinstall the Guide, and then reinsert the Cannula into the patient.

Following placement of the Cannula, the Retrieval Device is passed down and advanced out of the distal end of the Cannula.



Pass Retrieval Device

The looped end of the Retrieval Device is then retrieved through the vaginal dissection and pulled out of the vagina with an instrument or a finger.



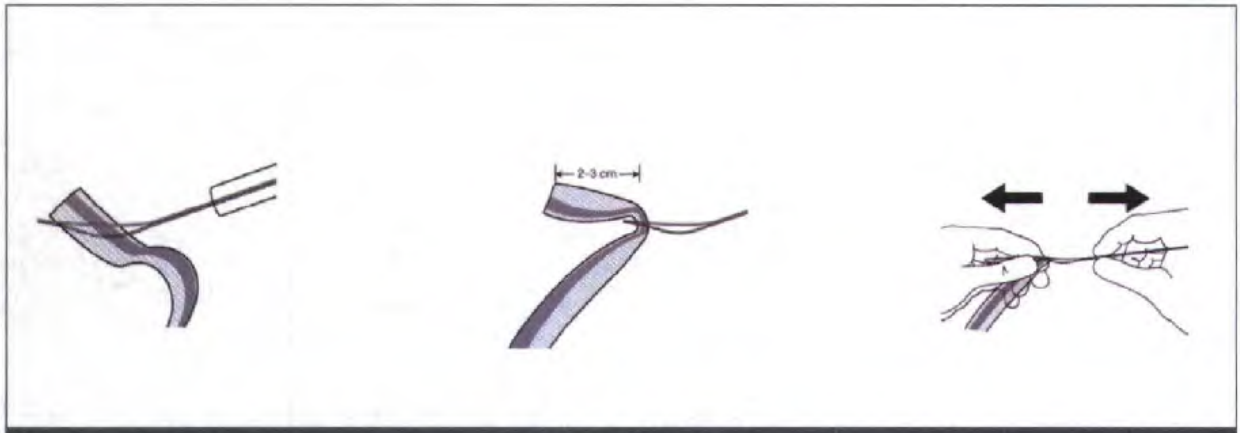
Retrieve the Retrieval Device

The proximal end of the Retrieval Device can then be passed through the loop and secured to the drape or a retractor with a hemostat, thus reserving the Retrieval Device for later use in pulling the Posterior Implant strap into position. Optionally, the Cannulas may also be secured when placed in order to limit movement as the other Cannulas are installed. Care should be taken to avoid movement of the Cannulas following placement.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

Placement of the Posterior Implant

To install the Posterior Implant, the distal ends of the straps are captured in the loops at the end of the Retrieval Devices. The loops are then pulled through the Cannulas to the proximal exit.

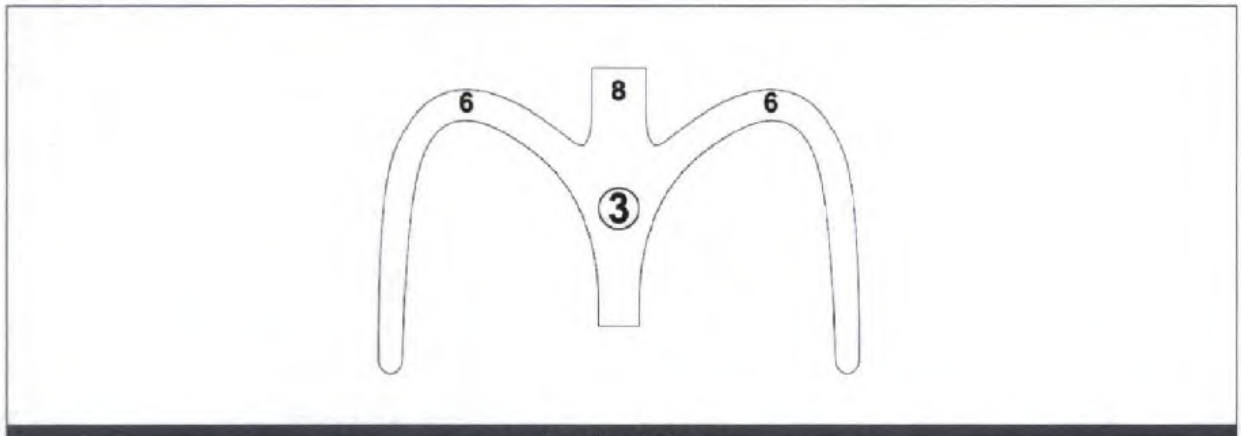


Capture distal ends

The Posterior Implant can be positioned once both straps have been retrieved. Optimally, the Posterior Implant will be positioned tension-free above the rectum with its lateral edges against the anterior face of the levator ani muscles.

Minor reductions in Posterior Implant length should be made at this point to ensure proper fit. If desired, sutures may be used bilaterally on the levator ani at the external edge of the Posterior Implant to ensure aid in positioning. A further fine adjustment of the tension and position of the Posterior Implant may be performed following closure of the vaginal incisions at the end of the procedure.

Alternatively, the straps (6) of the Posterior Implant may be fixated directly to the superficial aspect of the sacrospinous ligament. This can be accomplished by trimming the distal portion of these straps to the proper length and performing fixation with suture or alternative fixation means.



Posterior Implant

The Anterior Segment (8) of the Posterior Implant can be left free, or positioned above the Pouch of Douglas, or attached to the cardinal or uterosacral ligaments according to the surgeon's preference.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

Vaginal Closure and Final Adjustment

Closure of the vaginal incisions can now be made according to surgeon's preference. The straps should now be used to make any required additional fine adjustment to the Posterior Implant position, taking care to not place the mesh under tension. Following proper positioning, the Cannulas can be carefully withdrawn.

The ends of the straps extending out of the cutaneous incisions of the obturator foramen should be trimmed at the level of the dermis. These incisions are then closed according to surgeon's preference.

Posterior Repair with Uterine Preservation

The following includes important differences associated with the procedure when the uterus is preserved.

Posterior Vaginal Incision

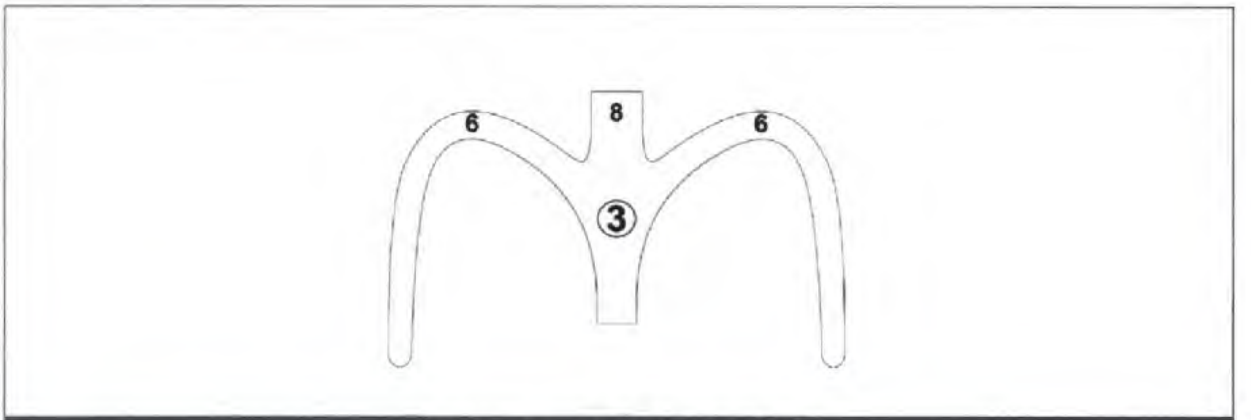
The recommended incision for this repair is a sagittal colpotomy of the lower half of the vagina ending at the vulva. Alternatively, the dissection could be performed through a transverse incision made at the junction of the perineal skin and the vagina. If a perineal repair is indicated, a diamond-shaped incision overlapping the lower half of the sagittal colpotomy and the posterior perineum is recommended.

Posterior Dissection

The posterior dissection is performed up to the uterine isthmus.

Posterior Mesh Fixation

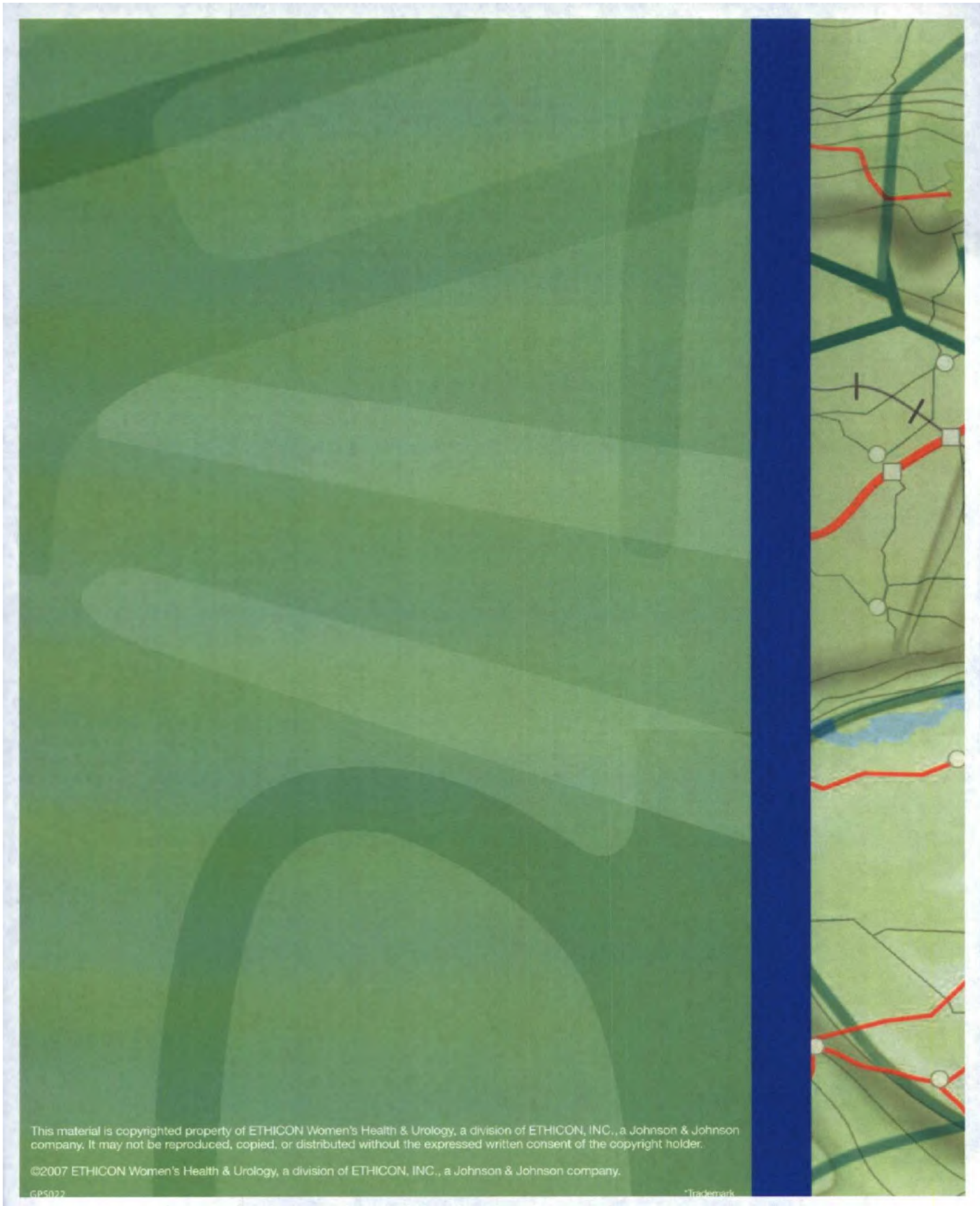
The Anterior Segment (8) of the Posterior Implant is attached to the posterior face of the uterine isthmus about 2 cm above the cervix with a single stitch of PROLENE suture.



Anterior Segment (8) of Posterior Implant

Associated Procedures

Whenever needed, a perineal repair or a suburethral sling for the treatment of stress urinary incontinence can be performed. The suburethral sling can be passed through the retropubic space or obturator foramen depending on surgeon's preference.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CLINICAL DATA Summary

Author	Patients	Follow-up	Exposure*	Success	Complications	
Cosson Et Al	90	12mo	9 (10%) 5 (5.6%)	74 (81.6%)	Rectal injury Bleeding Fistula (VV)	1 2 1
Fatton Et Al	110	3mo	5 (4.7%)	105 (95.3%)	Cystotomy Hematoma Retention	1 2 6
Murphy Et Al	89	5mo	0 (0%)	84 (94.4%)	Cystotomy	2
Hinoul Et Al	29	6mo	2 (6.9%)	28 (96.5%)	Cystotomy	1
Withagen Et Al	43	6mo	2 (4.7%)	35 (81.4%)	Rectal injury Cystotomy Retention	1 2 1
Groenen Et Al[1]	26	2mo	1 (3.8%)	26 (100%)	Retention	5
Perscheler Et Al[1]	80	N/A	8 (10%) 5 (6.25%)	N/A	Hematoma Cystotomy	2 2
Rivera Et Al[2]	82	3mo	7 (11.7%)	N/A	Hematoma Bleeding	1 1
Total	549	6mo	34 (6.2%) 12 (2.6%)	81.4-100%	Rectal injury Bleeding Retention Cystotomy	1.7% 1.3% 6.7% 1.7%

* second figure is exposures requiring intervention

[1] All abstracts 2006 IUGA Int Urogynecol J 2006;17(s.2):S212(abstracts)
[2] All abstracts 2006 AUGS Int Urogynecol J 2006;17(S.3):S460(abstracts)

Author	Patients	Follow-up	De Novo Sexual Limitaion
Murphy et al[1]	89	5mo	2/38 (5.3%)
Fatton et al[2]	90	3mo	3/35 (8.5%)

[1] Murphy et al Int Urogynecol J 2006;17(s.2):S212(abstracts)
[2] Fatton et al Int Urogynecol J 2006;17(s.2):S273(abstracts)

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APPENDIX

Gynecare PROLIFT*

Pelvic Floor Repair Systems

Surgical Technique

SURGICAL TECHNIQUE

Principles of the Procedure

The objective of the PROLIFT procedure is to achieve a complete anatomic repair of pelvic floor defects in a standardized way. Depending on the site of the defect and surgeon's preference, the repair can either be anterior, posterior, or total. The repair is achieved by the placement of one or two synthetic non-absorbable polypropylene (GYNEMESH* PS) mesh implants via a vaginal approach.

The procedure requires a wide dissection in order to properly place the relatively large implants. These implants are designed to cover all existing or potential pelvic floor defects in a tension-free way.

Hysterectomy

Surgeon's preference and the patient's needs will determine if a concurrent hysterectomy is required. Peritonealization is recommended to avoid contact of the mesh to the bowel when a hysterectomy is performed. Retrospective data analysis suggests that the rate of mesh exposure may be higher when performing the TransVaginal Mesh (TVM) procedure with concurrent hysterectomy.

Vaginal Incisions

The principles regarding vaginal incisions include minimizing the size of the vaginal incisions and avoiding T-shaped incisions. Thus, when a vaginal hysterectomy is performed, it is recommended to avoid complementary sagittal incisions. This will dictate that the bladder dissection be performed through the pericervical incision.

Mesh Fixation

The implants are held in place by friction acting on the associated straps passing through tissue. If required, additional stitches may be used along with the straps to aid in proper placement of the implant. It is essential to install all of the available mesh straps to properly place and secure the implants.

Vaginal Preservation

It is recommended to avoid large vaginal excisions and fixation of the vagina to the implant.

Procedural Description

The procedure must be postponed if one of the following conditions is present:

- Vaginal infection
- Vaginal erosions
- Urinary infection

Additionally, the procedure should also be cancelled if a perioperative bladder or rectal injury occurs.

Preoperative Preparation

Repairs performed with the GYNECARE PROLIFT Pelvic Floor Repair System may be carried out under general or regional anesthesia according to surgeon's preference. Systematic preoperative antibiotic prophylaxis may be administered according to surgeon's preference.

The following steps are recommended prior to the start of the procedure:

- Antiseptic vaginal preparation
- Shaving or clipping of the pubic or hair
- Bowel preparation or preoperative enema
- Cleansing of the entire surgical area with appropriate antiseptic

The following steps are to be considered optional:

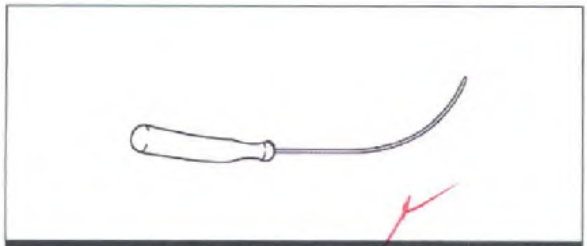
- Placement of an in-dwelling catheter after a urine culture has been performed
- Placement of lubricated packing in the rectum
- Infiltration of the vaginal wall by saline with a vasoconstrictive solution to ease dissection and reduce bleeding
- Administration of antibiotics

Patient Positioning

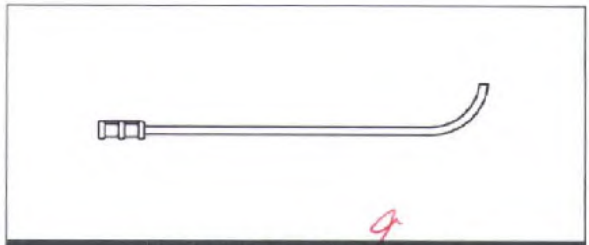
The patient should be placed in the lithotomy position with her buttocks slightly overlapping the table and her thighs flexed at approximately 90 degrees in relation to the plane of the table.

GYNECARE PROLIFT* Repair System

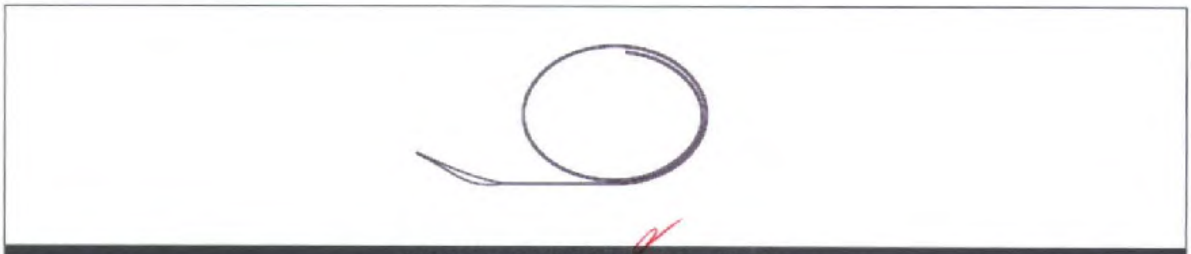
Nomenclature



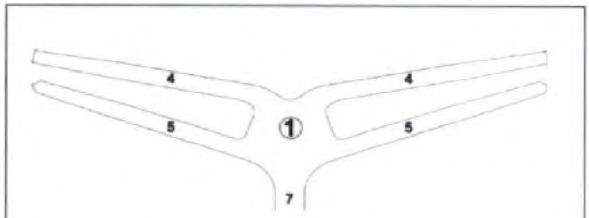
GYNECARE PROLIFT* Guide



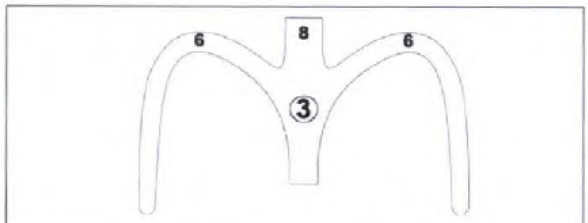
GYNECARE PROLIFT* Cannula



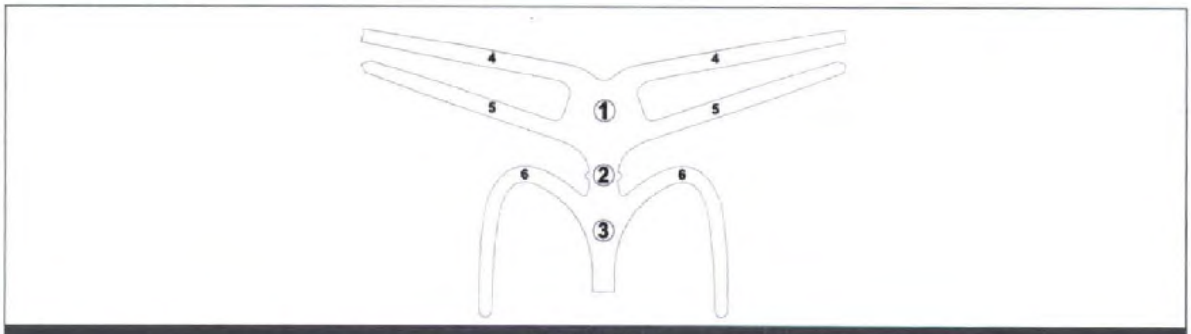
GYNECARE PROLIFT* Retrieval Device



Anterior Implant



Posterior Implant



Total Implant

TOTAL REPAIR with Vaginal Hysterectomy

The procedure begins with a vaginal hysterectomy with or without adnexectomy, followed by an anterior repair and then a posterior repair. Retrospective data analysis suggests that the rate of mesh exposure may be higher when performing the TVM procedure with concurrent hysterectomy.

Vaginal Incision and Hysterectomy

A standard vaginal hysterectomy is performed through a pericervical incision. It is recommended that users identify and retain the uterosacral ligaments or other elements of the cardinal ligament complex. These structures can later be interposed between the implant and the vagina or attached to the edges of the Total Implant according to surgeon's preference. Care must be taken to close the peritoneum.

The ensuing procedure steps will ideally be performed without any complementary sagittal incision whenever possible. Alternatively, a sagittal anterior colpotomy starting at the vaginal incision and ending approximately 1 cm from the bladder neck could be used if needed.

Anterior Dissection

Grasp and maintain control of the anterior vaginal wall with a series of ~~three~~ 3 atraumatic forceps.

Perform a dissection of the entire thickness of the anterior vaginal wall. It is preferred to leave Halban's fascia (pubocervical fascia) on the vaginal wall. Dissection begins from the vaginal incision and should continue up to a point approximately 3-4 cm from the urinary meatus, in order to preserve and protect the region of the bladder neck.

Dissect the bladder laterally up to the vaginal cul de sac. When a defect exists, a finger will easily penetrate the paravesical fossa (paravaginal space). If no defect is evident, an orifice must be created in the fascia using blunt dissection techniques. This dissection is the starting point for a broad lateral dissection of the bladder, which will make it possible to identify the whole length of the arcus tendineus fascia pelvis (ATFP), which extends from the posterior aspect of the pubic arch to the ischial spine. If the ATFP cannot easily be identified, then palpation via a finger in the vagina from the pubic arch to the ischial spine should be used to ensure that straps 4 and 5 of the Anterior Segment (1) pass through at this level.

Anterior Segment (1) of Total Implant

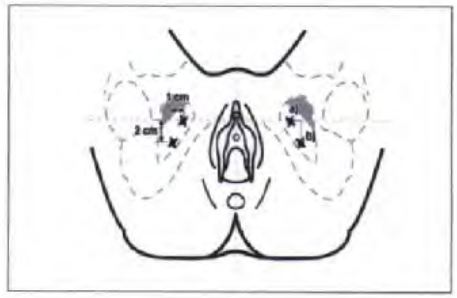
At this point, if required, plication of the bladder is performed in order to reduce the cystocele.

Preparation for Placement of the Anterior Segment

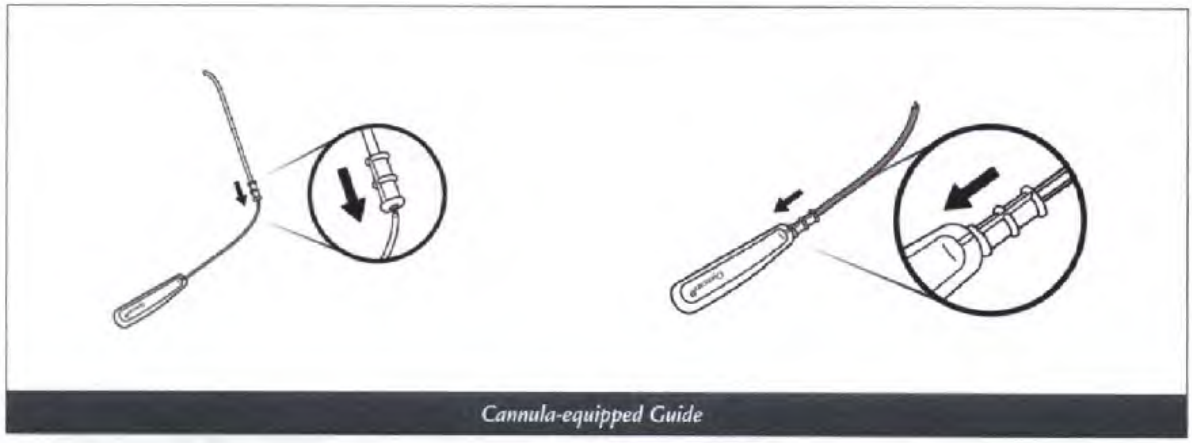
The following should be performed on the patient's left and right.

The Superficial Straps

The limits of the obturator foramen are identified by palpation between the thumb and index finger of the obturator membrane where it comes into contact with the bony boundaries. The cutaneous incision for passage of the superficial strap of the Anterior Segment (4) is made in the anteromedial edge of the obturator foramen, at the level of the urethral meatus. A 4 mm incision is made to enable the Guide with the Cannula installed to pass through the skin without tearing. It is helpful to mark the edge of the obturator foramen with a skin marking pen as a guide for the entrance locations.

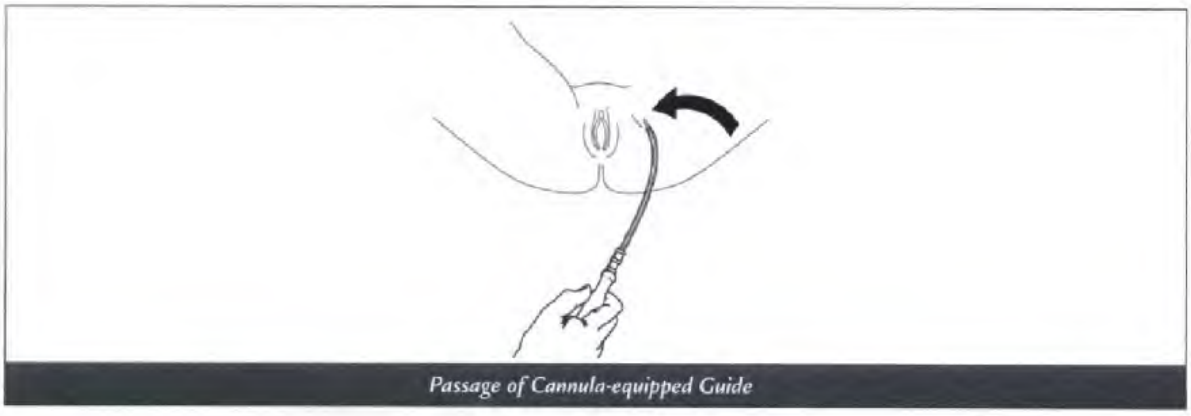


At the start of the passage, the Cannula-equipped Guide will perforate the obturator externus muscle and then the obturator membrane. The device should then be advanced medially through the obturator membrane and pass through the obturator internus muscle approximately 1 cm from the proximal (prepubic) end of the ATFP.

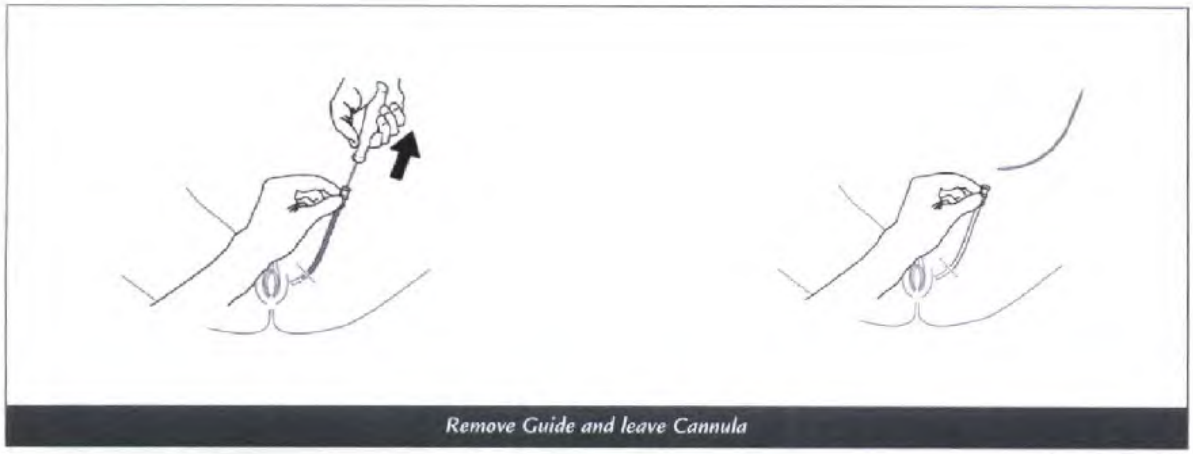


Cannula-equipped Guide

A finger positioned inside the vaginal dissection should always be used to ensure that the device follows the proper path and to provide protection to the bladder. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. Care should be taken to keep the Cannula in position, as the Guide is withdrawn to ensure that the tip of the Cannula remains slightly extended out of the tissue passage and the Cannula is not advanced further into the patient.



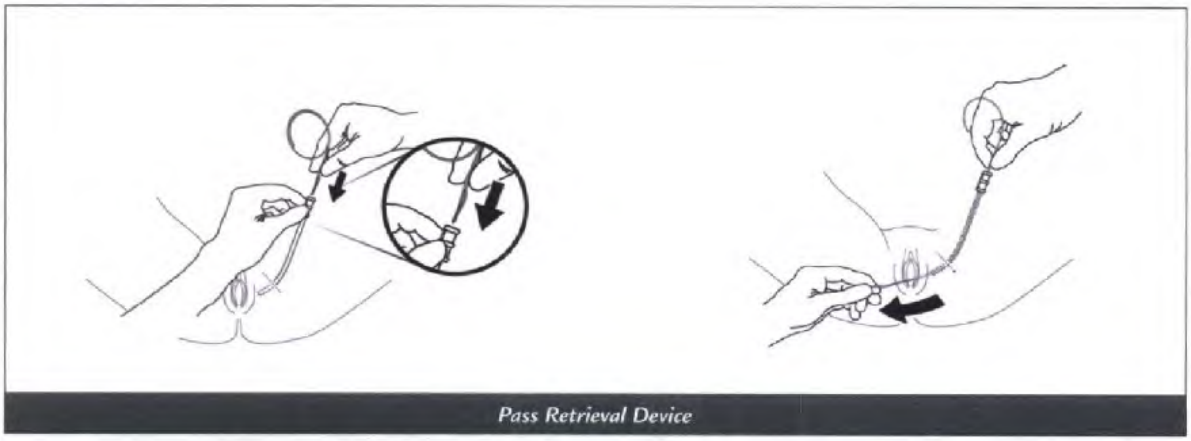
Passage of Cannula-equipped Guide



Remove Guide and leave Cannula

Once the Guide has been removed from the cannula, do not attempt to reinsert. Instead, remove the Cannula from the patient, reinstall the Guide, and then reinsert the Cannula into the patient.

Following placement of the Cannula, the Retrieval Device is passed down and advanced out of the distal end of the installed Cannula. The looped end of the Retrieval Device is then retrieved through the vaginal dissection and pulled out of the vagina with an instrument or a finger.

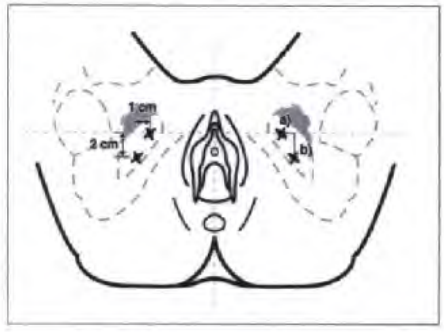


Pass Retrieval Device

The proximal end of the Retrieval Device can then be passed through the loop and secured to the drape or a retractor, thus reserving the Retrieval Device for later use in pulling the Total Implant strap into position. Optionally, the Cannulas may also be secured when placed in order to limit movement as the other Cannulas are installed. Care should be taken to avoid movement of the Cannulas following placement.

The Deep Straps

For placement of the deep strap of the Anterior Segment, a second cutaneous incision is made 1 cm lateral and 2 cm below the preceding incision at the posterolateral edge of the obturator foramen. To provide protection of the bladder, a Breisky or similar long retractor may be placed in the dissection. The Guide and Cannula are then inserted through the obturator externus muscle and then through the obturator membrane. The device should follow a downward trajectory once it passes through the obturator membrane. This movement will enable the Cannula-equipped Guide to emerge through the obturator internus muscle at the bottom of the paravesical fossa behind the ATFP, approximately 1 cm from the ischial spine.



A finger positioned inside the vaginal dissection should be used to ensure that the Guide follows the proper path and to provide protection to the bladder. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. The Retrieval Device is then installed and secured as described above.

Posterior Vaginal Incision

The recommended incision for this repair is a complementary sagittal colpotomy of the lower / distal half of the vagina ending at the vulva. Alternatively, the dissection can be performed through a complementary transverse incision made at the junction of the perineal skin and the vagina. If a perineal repair is indicated, a diamond-shaped incision overlapping the lower half of the sagittal colpotomy and the posterior perineum is recommended.

Posterior Dissection

Care should be taken when separating the rectum from the entire thickness of the vagina.

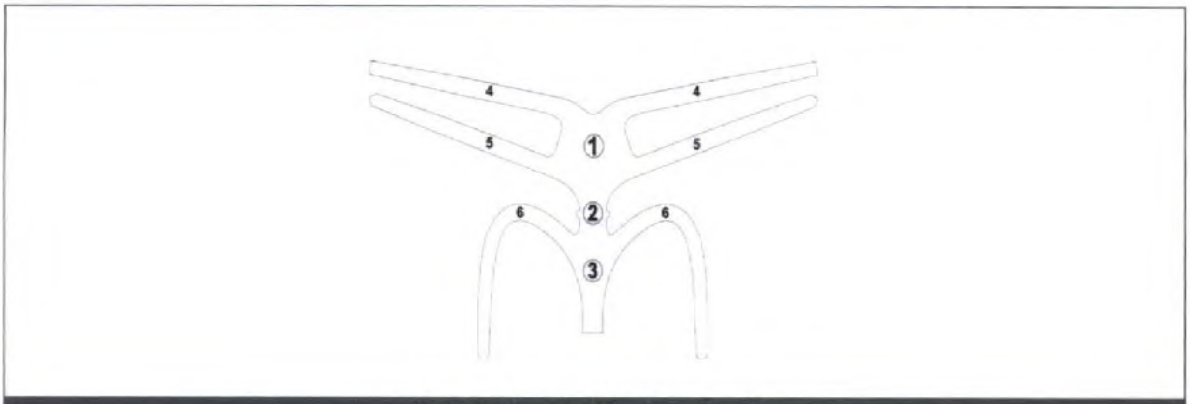
Dissection of the entire thickness of the posterior vaginal wall should be performed starting from the vaginal incision and continued up to the apex of the vagina. Laterally, the dissection opens the pararectal spaces and follows the space between the rectum and the levator ani muscle until the sacrospinous ligament can be palpated.

Generally, this dissection enables placement of a Breisky retractor or other such instrument which will be useful during later activities. Further deep dissection should then be performed to expose both sides of the sacrospinous ligament at the level of the ischial spine.

At this point, if required, a plication of the prerectal fascia in order to reduce the rectocele should be performed. Any required reductions of enteroceles should also be performed at this time.

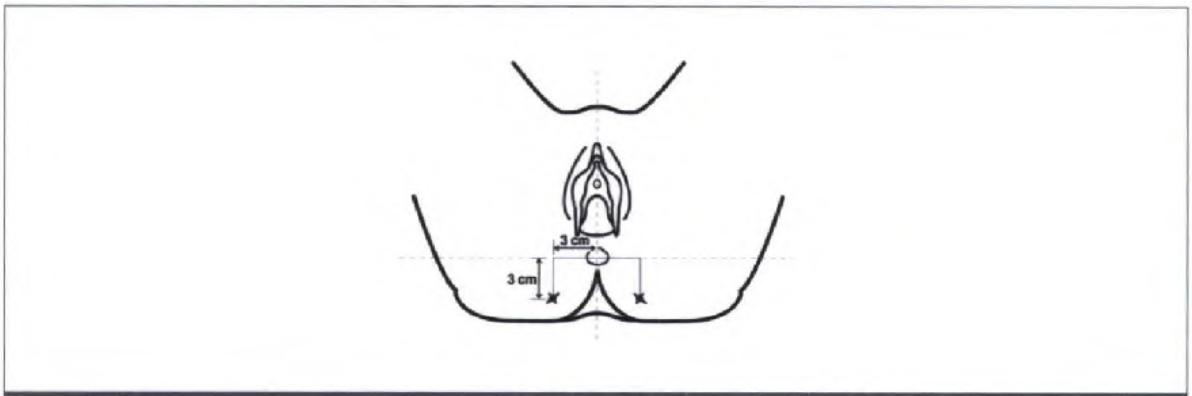
Preparation for Placement of the Posterior Segment

The following should be performed on the patient's left and right.



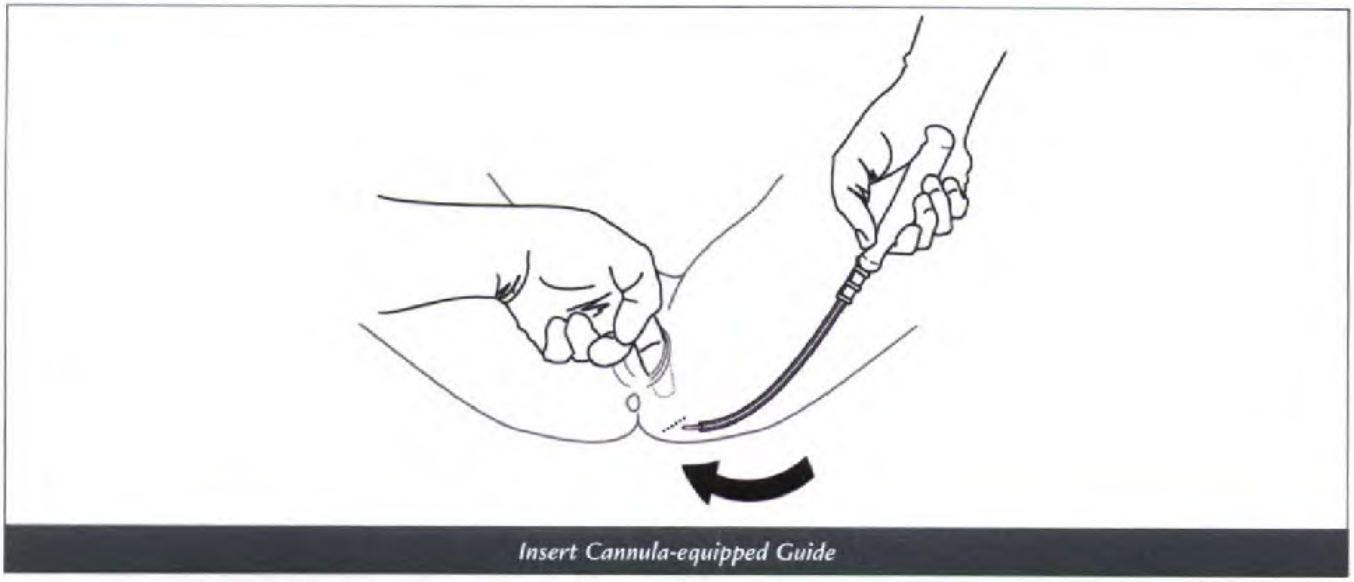
Posterior Segment (3) of Total Implant

The Posterior Segment (3) of the Total Implant is to be positioned in the ischioanal fossa, inferior to levator ani muscle, and secured by passage of the straps through the sacrospinous ligament and coccygeus muscles. To accomplish this, a 4 mm cutaneous incision is made approximately 3 cm lateral and 3 cm down from the anus.



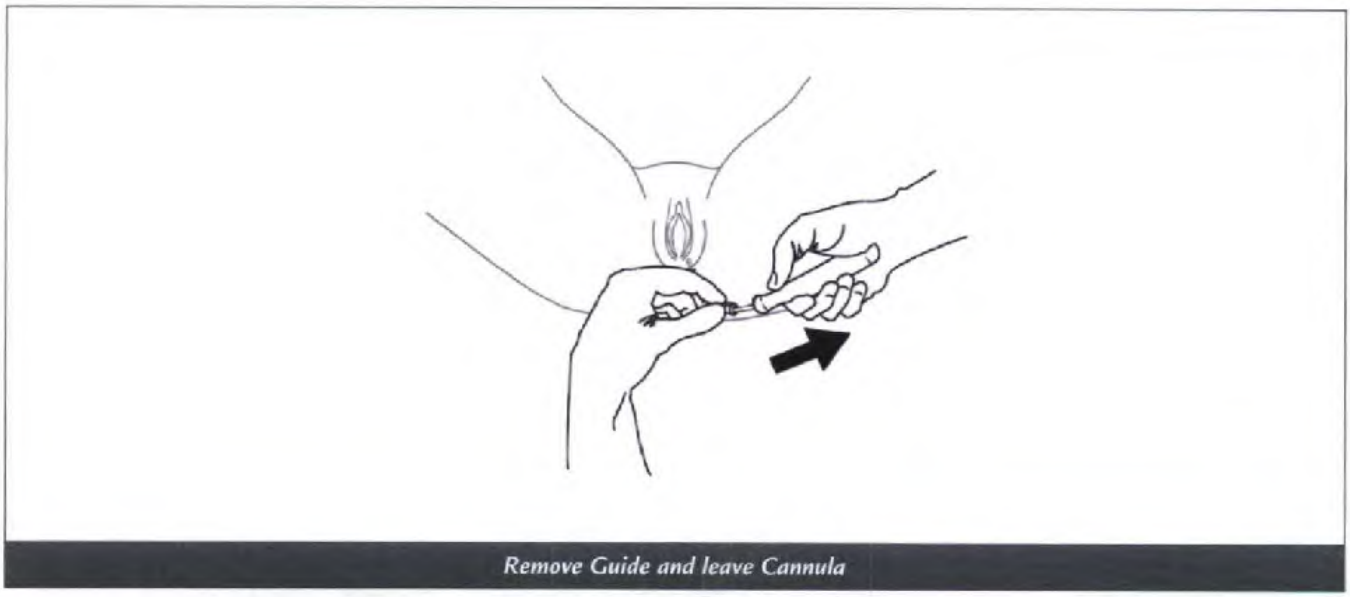
Posterior incision

The Cannula-equipped Guide is inserted into the incision, passed through the buttocks, and continued below the plane of the levator ani muscle, constantly controlled by the fingers within the vaginal dissection. The rectum should be pulled back and kept at a distance, either manually, or by using a retractor to prevent damage from the device.



Insert Cannula-equipped Guide

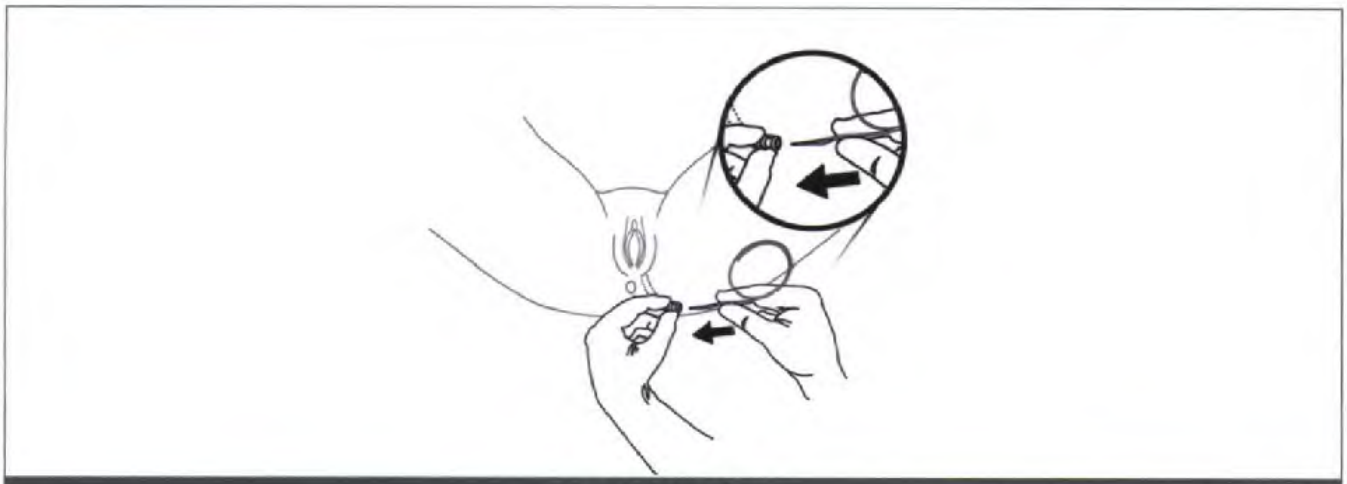
The Cannula-equipped Guide is advanced until it is in contact with the inferior side of the sacrospinous ligament approximately 3-4 cm medial to the ischial spine. It is then pushed through the sacrospinous ligament under digital control, thus exposing the tip of the Guide and Cannula. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. Care should be taken to keep the Cannula in position as the Guide is withdrawn to ensure that the tip of the Cannula remains extended out of the tissue passage and the Cannula is not advanced further into the patient.



Remove Guide and leave Cannula

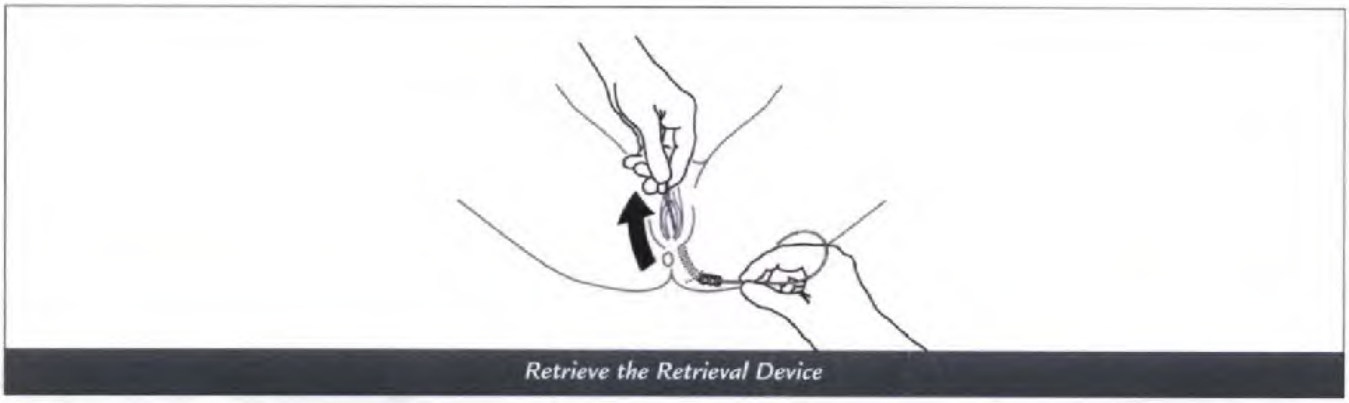
Once the Guide has been removed from the cannula, do not attempt to reinsert. Instead, remove the Cannula from the patient, reinstall the Guide, and then reinsert the Cannula into the patient.

Following placement of the Cannula, the Retrieval Device is passed down and advanced out of the distal end of the Cannula.



Pass Retrieval Device

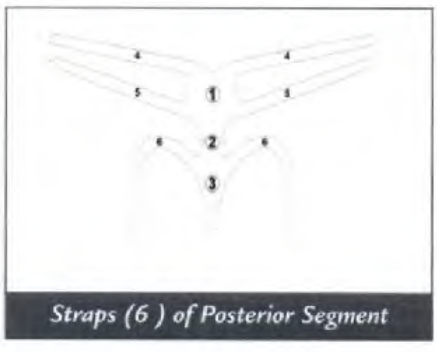
The looped end of the Retrieval Device is then retrieved through the vaginal dissection and pulled out of the vagina with an instrument or a finger.



Retrieve the Retrieval Device

The proximal end of the Retrieval Device can then be passed through the loop and secured to the drape or a retractor with a hemostat, thus reserving the Retrieval Device for later use in pulling the Total Implant strap into position. Optionally, the Cannulas may also be secured when placed in order to limit movement as the other Cannulas are installed. Care should be taken to avoid movement of the Cannulas following placement.

An alternative approach is to directly fixate the Posterior Segment straps (6) to the superficial aspect of the sacrospinous ligament. This can be accomplished by trimming the distal portion of these straps to the proper length and performing fixation with suture or alternative fixation means.

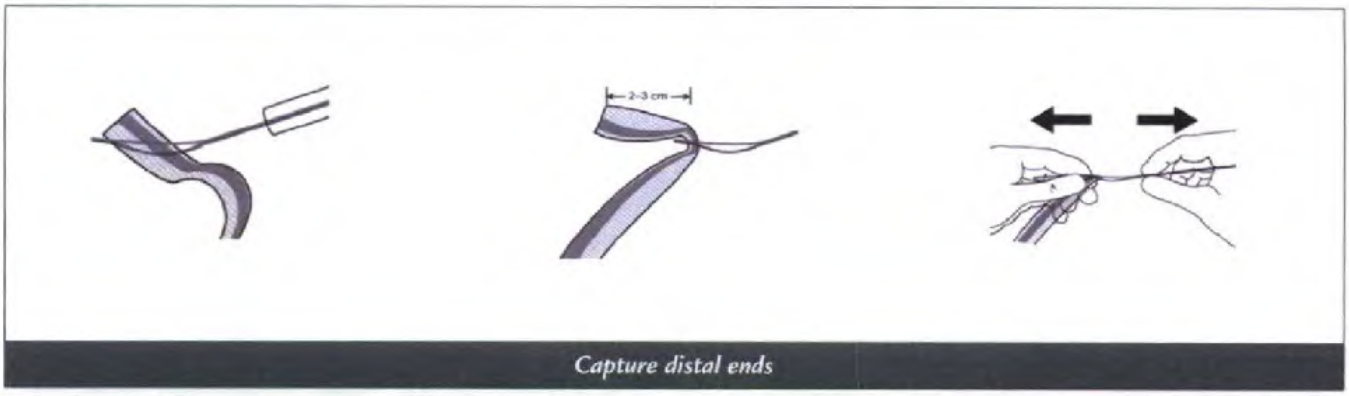


Straps (6) of Posterior Segment

Placement of the Total Implant

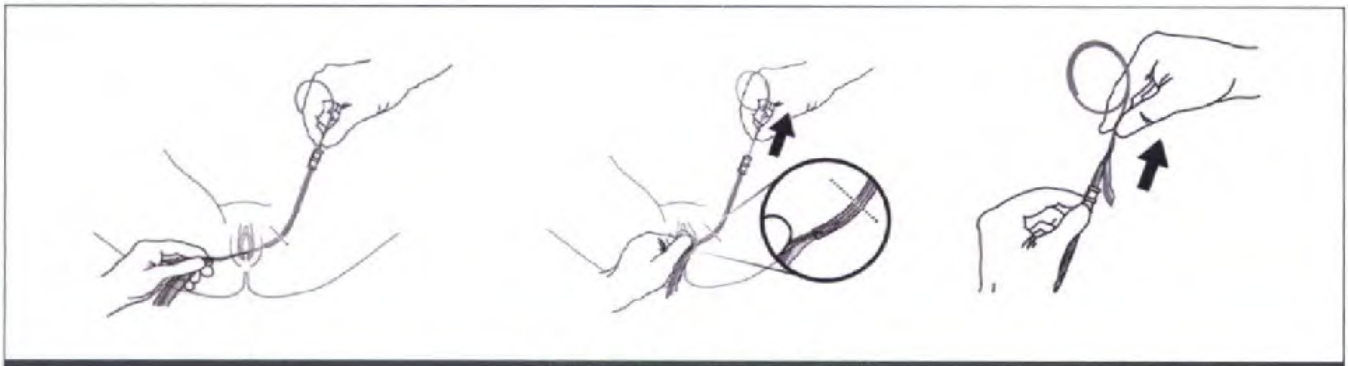
Anterior Segment Placement

Placement of the Total Implant starts anteriorly. The distal ends of the Total Implant straps are sequentially captured in the loops at the end of the Retrieval Devices.



Capture distal ends

The loops are then pulled through the Cannulas to the proximal exit. The ends of the straps of the Anterior Segment are uniquely shaped with the superficial straps having squared ends and the deep straps having triangular ends.



Pull loops through Cannula

Optimally, the Anterior Segment of the Total Implant will be positioned tension-free under the bladder while ensuring lateral contact against the ATFP. Lateral contact of the Total Implant to the ATFP should be carefully verified.

If required, small reductions in the dimensions of the Total Implant to ensure proper fit should be performed at this point.

Further fine adjustment of the tension and position of the Total Implant may be performed following closure of the vaginal incisions at the end of the procedure.

Fixing the Total Implant at each of the pubic insertions of the puborectalis muscle with sutures is optional. If the surgeon elects to do this, it is essential that the anterior notch of the Total Implant leaves the neck of the bladder largely free. Additional fixations remain optional.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh, it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

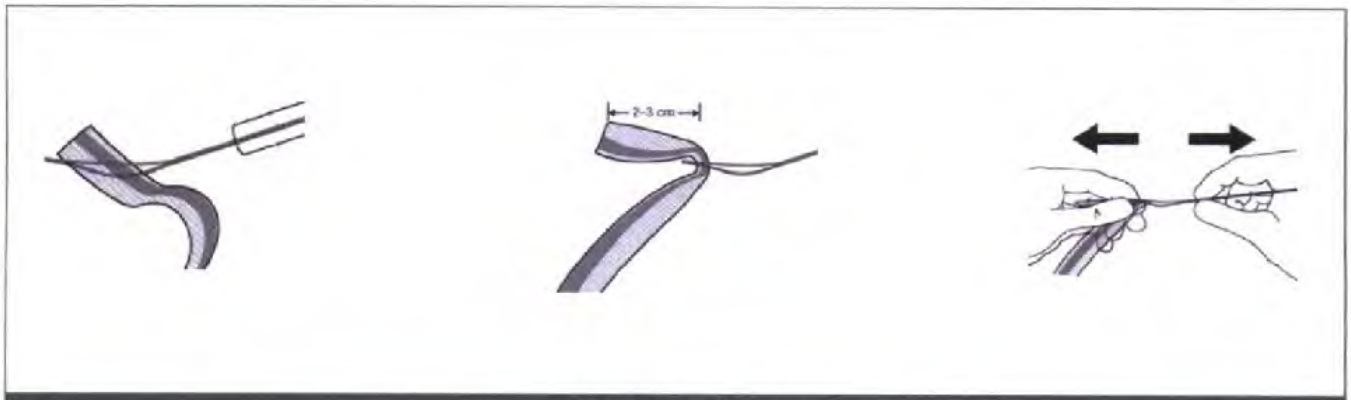
Middle Segment Placement

The Middle Segment (2) of the Total Implant should be positioned in the posterior dissection behind the vaginal apex. The uterosacral ligaments or other elements of the cardinal ligament complex can be either interposed between the Total Implant and the vagina or attached to the edges of the Total Implant according to surgeon's preference.

Middle Segment (2) of Total Implant

Posterior Segment Placement

Installation of the Posterior Segment of the Total Implant requires the distal ends of the straps to be sequentially captured in the loops at the end of the Retrieval Devices.



Capture distal ends

The loops are then pulled through the Cannulas to the proximal exit. The Posterior Segment can be positioned once both straps have been retrieved.

Optimally, the Posterior Segment of the Total Implant will be positioned tension-free above the rectum with its lateral edges against the superior surface of the levator ani muscles. Minor reductions in Total Implant length should be made at this point, if required, to ensure proper fit. If desired, sutures may be used bilaterally on the levator ani muscles at the external edge of the Total Implant to ensure aid in positioning.

Further fine adjustment of the tension and position of the Total Implant may be performed following closure of the vaginal incisions at the end of the procedure.

Straps (6) of Posterior Segment

An alternative approach to fixation of the Posterior Segment is to directly fixate the straps (6) to the superficial aspect of the sacrospinous ligament. This can be accomplished by trimming the distal portion of the straps (6) to the proper length and fixating with suture or other alternative means.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh, it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

Vaginal Closure and Final Adjustment

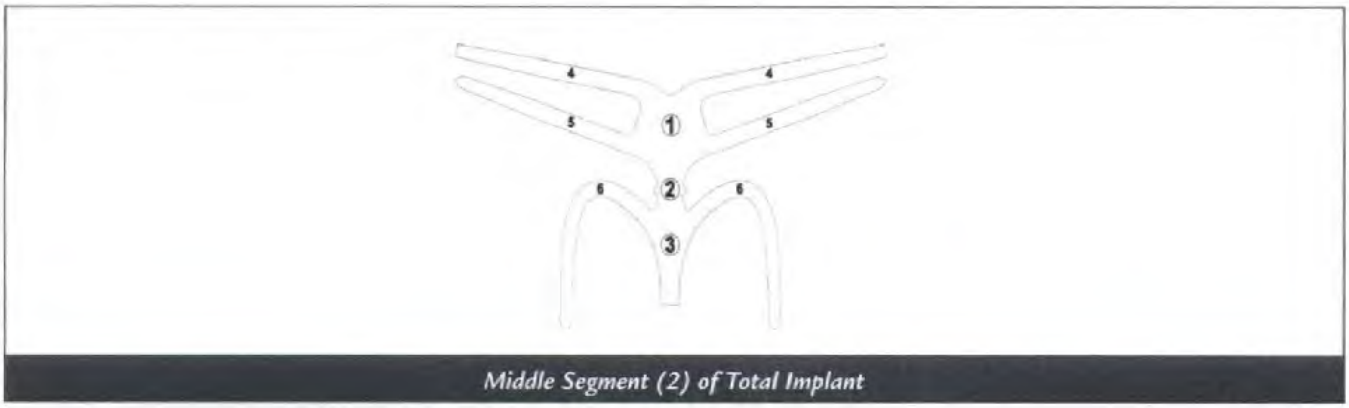
Closure of the vaginal incisions can be made according to surgeon's preference. The straps should be used to make any required additional fine adjustment to the Total Implant position, taking care to not place the mesh under tension. The Cannulas can be withdrawn once the Total Implant is properly positioned. The ends of the Total Implant straps extending out of the cutaneous incisions should be trimmed at the level of the dermis. These incisions are closed according to surgeon's preference.

TOTAL REPAIR with Uterine Preservation

Surgeon's preference and the patient's needs will determine if a concurrent hysterectomy is required. If the uterus is maintained, the following information includes important differences of the procedure previously described.

Implant Preparation

The Total Implant must be cut at the midpoint of the Middle Segment (2).



Middle Segment (2) of Total Implant

Anterior Vaginal Incision

The recommended incision for this repair is a sagittal colpotomy starting 1 cm below the cervix and ending approximately 1 cm from the bladder neck. Alternatively, a transverse incision could be used.

Anterior Mesh Fixation

The posterior part of the Anterior Segment should be attached to the anterior face of the uterine isthmus about 2 cm above the cervix with a single stitch of PROLENE suture.

Posterior Vaginal Incision

The recommended incision for this repair is a sagittal colpotomy of the lower half of the vagina ending at the vulva. Alternatively, the dissection could be performed through a transverse incision of the perineum made at the junction of the perineal skin and the vagina. If a perineal repair is indicated, a diamond-shaped incision overlapping the lower half of the sagittal colpotomy and the posterior perineum is recommended.

Posterior Mesh Fixation

The anterior portion of the Posterior Segment is attached to the posterior face of the uterine isthmus about 2 cm above the cervix with a single stitch of PROLENE suture.

TOTAL REPAIR in Case of Previous Hysterectomy

The following details important differences associated with women who have had a prior hysterectomy.

Vaginal Incision

The recommended incision for this repair is a sagittal colpotomy starting about 1 cm above the vaginal scar and ending approximately 1 cm from the bladder neck. Alternatively, a transverse incision could be used.

Mesh Fixation

Generally, there is no structure that can readily be identified for attachment to the central region of the implant. If the uterosacral ligaments exist, they can be used in the same way as previously described.

TOTAL REPAIR in the Absence of a Posterior Defect (Anterior / Apical Repair)

When the patient presents the association of a cystocele and a hysterocele or a vaginal vault prolapse but no significant posterior defect (rectocele), the PROLIFT Total Pelvic Floor Repair ~~kit~~ System may also be used to perform a combination anterior/apical repair.

This repair is accomplished by the following:

- Performing the required anterior and posterior incisions and dissection
- Removing the unneeded lower part of the Posterior Segment of the Total Implant (straps must be left intact)
- Placing the Anterior Segment per standard procedures
- Placing and fixing the Middle Segment per standard procedures
- Securing the straps of the abbreviated Posterior Segment to or through the sacrospinous ligament as previously described

The suspension of the uterus (in case of uterine preservation) or the vaginal vault (in case of concomitant or previous hysterectomy) relies on the Posterior Segment of the Total Implant.

In case of uterine conservation, the anterior part of the Posterior Segment of the Total Implant is attached to the posterior face of the uterine isthmus about 2 cm above the cervix with a single stitch of non absorbable monofilament suture.

ANTERIOR REPAIR with Hysterectomy

Vaginal Incision and Hysterectomy

A standard vaginal hysterectomy is performed through a pericervical incision. It is recommended that users identify and retain the uterosacral ligaments or other elements of the cardinal ligament complex. These structures can later be interposed between the Anterior Implant and the vagina or attached to the edges of the Anterior Implant according to surgeon's preference. Care must be taken to close the peritoneum.

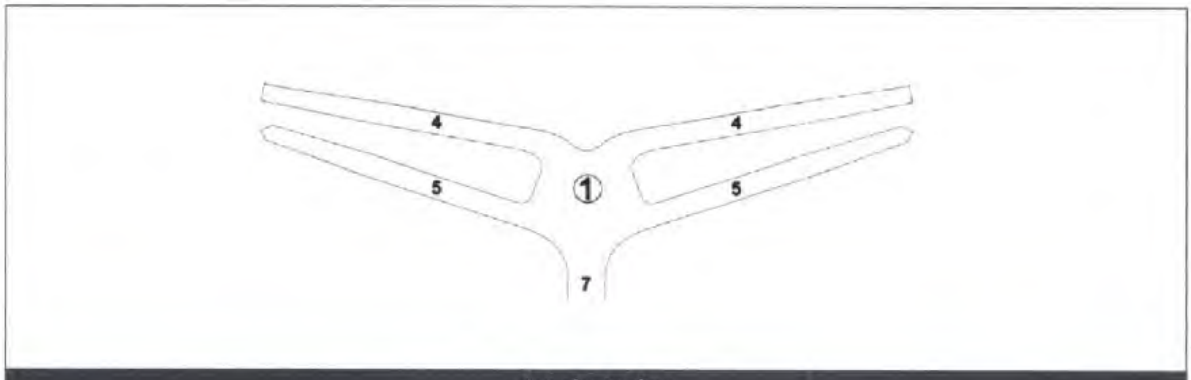
The next steps will ideally be performed without any complementary sagittal incision whenever possible. Alternatively, a sagittal anterior colpotomy starting at the vaginal incision and ending approximately 1 cm from the bladder neck could be used if needed.

Anterior Dissection

Grasp and maintain control of the anterior vaginal wall with a series of three atraumatic forceps.

Perform a dissection of the entire thickness of the anterior vaginal wall. It is preferred to leave Halban's fascia (pubocervical fascia) on the vaginal wall. Dissection begins from the vaginal incision and should continue up to a point approximately 3-4 cm from the urinary meatus, in order to preserve and protect the region of the bladder neck.

Dissect the bladder laterally up to the vaginal cul de sac. When a defect exists, a finger will easily penetrate the paravesical fossa (paravaginal space). If no defect is evident, an orifice must be created in the fascia using blunt dissection techniques. This dissection is the starting point for a broad lateral dissection of the bladder, which will make it possible to identify the whole length of the arcus tendineus fascia pelvis (ATFP), which extends from the posterior aspect of the pubic arch to the ischial spine. If the ATFP cannot easily be identified, then palpation via a finger in the vagina from the pubic arch to the ischial spine should be used to ensure that straps 4 and 5 of the Anterior Implant pass through at this level.

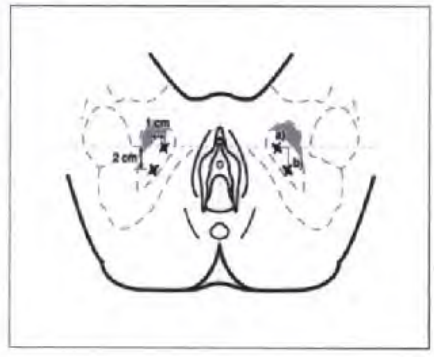


Anterior Implant

At this point, if required, plication of the bladder is performed in order to reduce the cystocele.

Preparation for Placement of the Anterior Implant

The following should be performed on the patient's left and right.

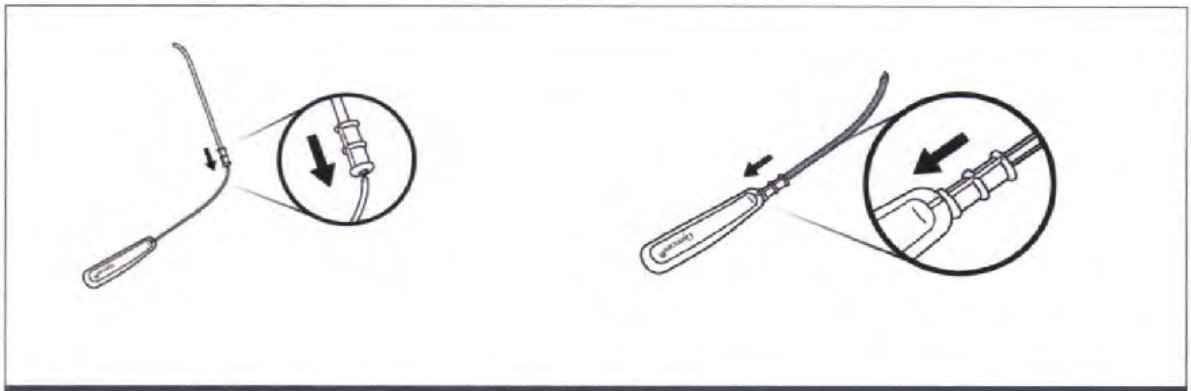


The Superficial Straps

The limits of the obturator foramen are identified by palpation between the thumb and index finger of the obturator membrane where it comes into contact with the bony boundaries.

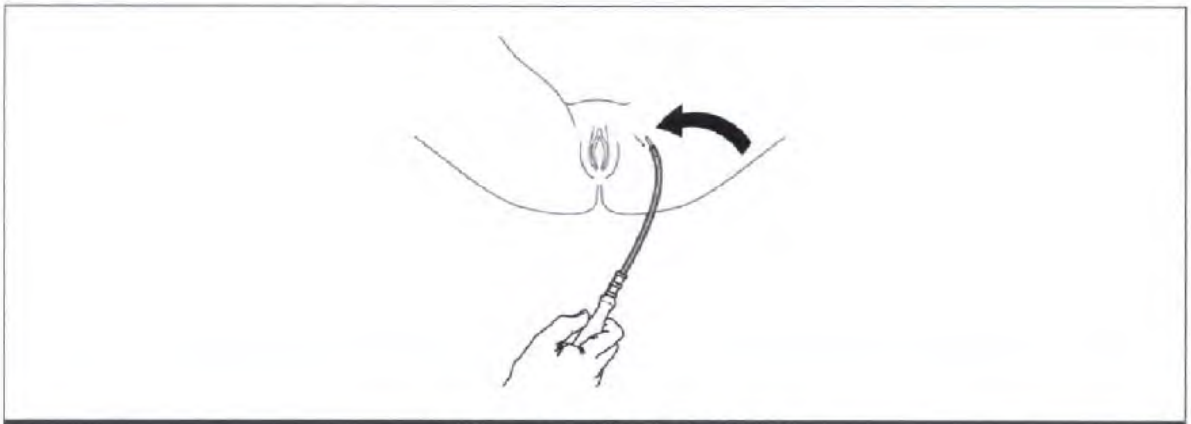
The cutaneous incision for passage of the superficial strap (4) of the Anterior Implant is made in the anteromedial edge of the obturator foramen, at the level of the urethral meatus. A 4 mm incision is made to enable the Guide with the Cannula installed to pass through the skin without tearing. It is helpful to mark the edge of the obturator foramen with a skin marking pen as a guide for the entrance locations.

At the start of the passage, the Cannula-equipped Guide will perforate the obturator externus muscle and then the obturator membrane. The device should then be advanced medially through the obturator membrane and pass through the obturator internus muscle approximately 1 cm from the proximal (prepubic) end of the ATFP.

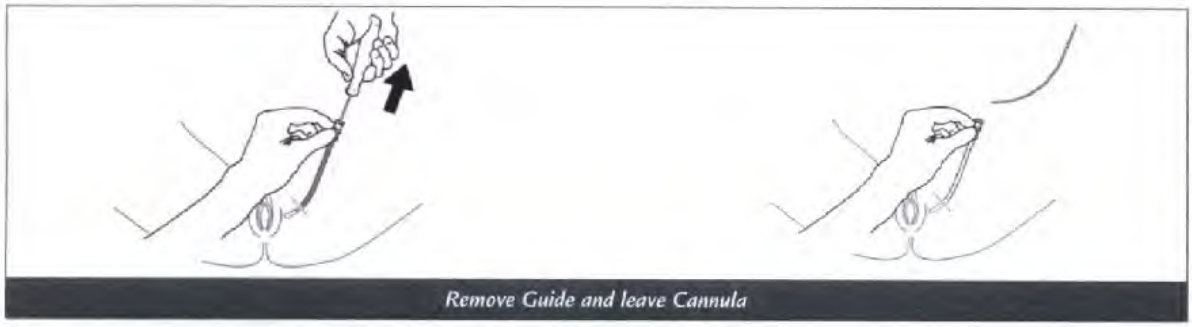


Cannula-equipped Guide

A finger positioned inside the vaginal dissection should always be used to ensure that the device follows the proper path and to provide protection to the bladder. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. Care should be taken to keep the Cannula in position as the Guide is withdrawn to ensure that the tip of the Cannula remains slightly extended out of the tissue passage and the Cannula is not advanced further into the patient.



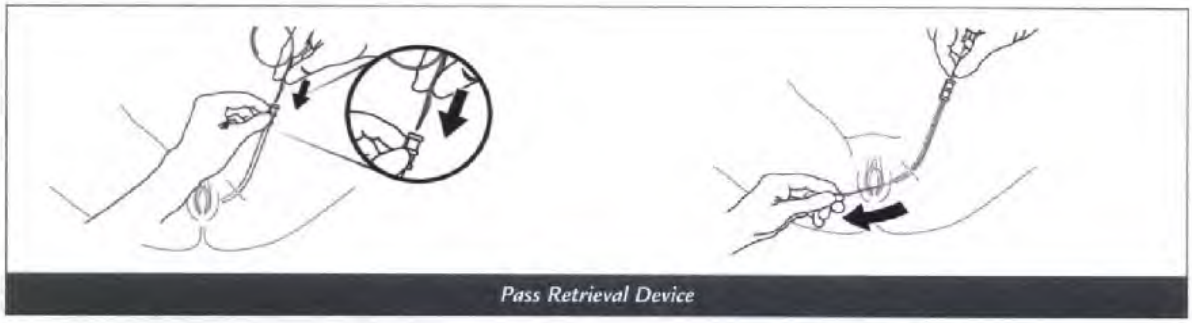
Passage of Cannula-equipped Guide



Remove Guide and leave Cannula

Once the Guide has been removed from the cannula, do not attempt to reinsert. Instead, remove the Cannula from the patient, reinstall the Guide, and then reinsert the Cannula into the patient.

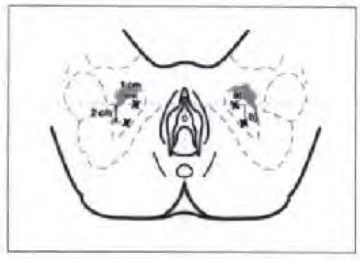
Following placement of the Cannula, the Retrieval Device is passed down and advanced out of the distal end of the installed Cannula. The looped end of the Retrieval Device is then retrieved through the vaginal dissection and pulled out of the vagina with an instrument or a finger.



Pass Retrieval Device

The proximal end of the Retrieval Device can then be passed through the loop and secured to the drape or a retractor, thus reserving the Retrieval Device for later use in pulling the Implant strap into position. Optionally, the Cannulas may also be secured when placed in order to limit movement as the other Cannulas are installed. Care should be taken to avoid movement of the Cannulas following placement.

The Deep Straps

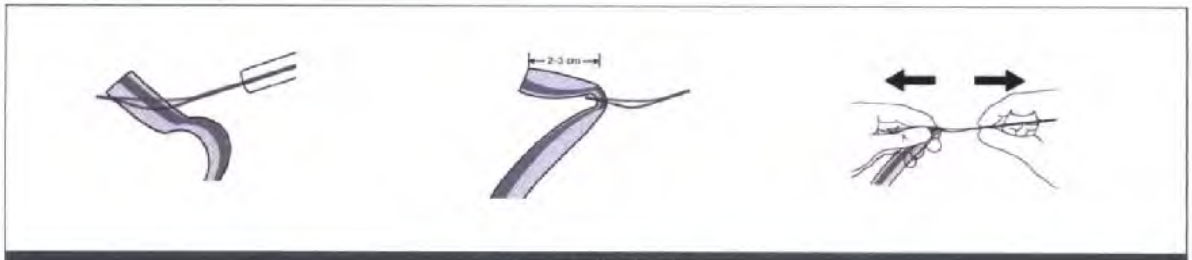


For placement of the deep strap (5) of the Anterior Implant, a second cutaneous incision is made 1 cm lateral and 2 cm below the preceding incision at the posterolateral edge of the obturator foramen. To provide protection of the bladder, a Breisky or similar long retractor may be placed in the dissection. The Guide and Cannula are then inserted through the obturator externus muscle and then through the obturator membrane. The device should follow a downward trajectory once it passes through the obturator membrane. This movement will enable the Cannula-equipped Guide to emerge through the obturator internus muscle at the bottom of the paravesical fossa behind the ATFP, approximately 1 cm from the ischial spine.

A finger positioned inside the vaginal dissection should be used to ensure that the Guide follows the proper path and to provide protection to the bladder. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. The Retrieval Device is then installed and secured as described above.

Placement of the Anterior Implant

The distal ends of the Anterior Implant straps are sequentially captured in the loops at the end of the Retrieval Devices.



Capture distal ends

The loops are then pulled through the Cannulas to the proximal exit. The ends of the straps of the Anterior Implant are uniquely shaped with the superficial straps having squared ends and the deep straps having triangular ends.

Pull loops through Cannula

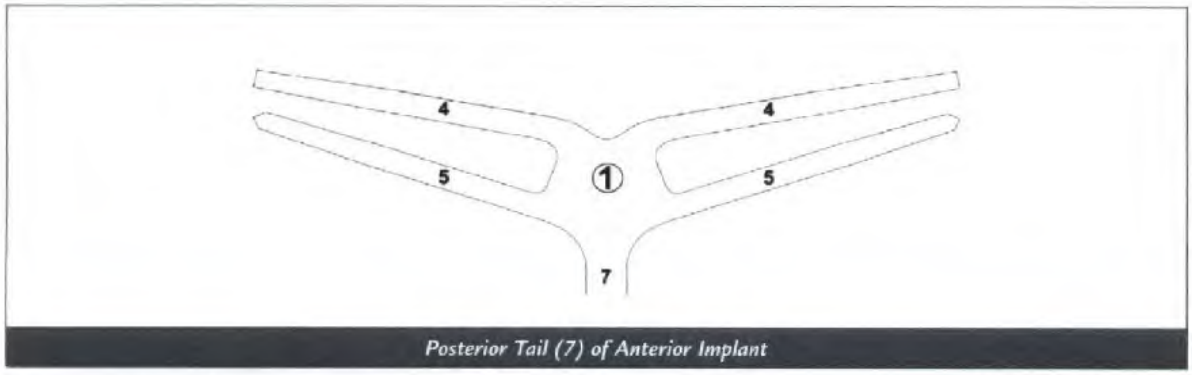
The Anterior Implant can be carefully positioned once all straps have been retrieved. Optimally, the Anterior Implant will be positioned tension-free under the bladder while ensuring lateral contact against the ATFP. Lateral contact of the Anterior Implant to the ATFP should be carefully verified. If required, small reductions in the dimensions of the Anterior Implant to ensure proper fit should be performed at this point.

Further fine adjustment of the tension and position of the Anterior Implant may be performed following closure of the vaginal incisions at the end of the procedure.

Fixing the Anterior Implant at each of the pubic insertions of the puborectalis muscle with sutures is optional. If the surgeon elects to do this, it is essential that the anterior notch of the Anterior Implant leaves the neck of the bladder largely free.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

The Posterior Tail (7) of the Anterior Implant can be left free, positioned under the inferior margin of the bladder, or attached to the parametrial / cardinal or uterosacral ligaments according to the surgeon's preference. Additional fixations remain optional.



Posterior Tail (7) of Anterior Implant

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

Vaginal Closure and Final Adjustment

Closure of the vaginal incisions can be made according to surgeon's preference. The straps should be used to make any required additional fine adjustment to implant position, taking care to not place the mesh under tension. Following proper positioning, the Cannulas can be carefully withdrawn.

The ends of the Anterior Implant straps extending out of the cutaneous incisions of the obturator foramen should be trimmed at the level of the dermis. These incisions are then closed according to surgeon's preference.

ANTERIOR REPAIR with Uterine Preservation

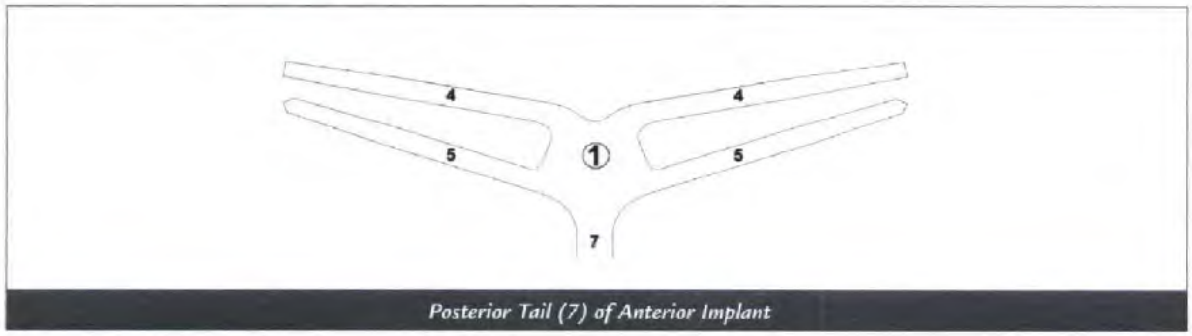
The following includes important differences associated with the procedure when the uterus is preserved:

Anterior Vaginal Incision

The recommended incision for this repair is a sagittal colpotomy starting 1 cm below the cervix and ending approximately 1 cm from the bladder neck. Alternatively, a transversal incision could be used.

Anterior Mesh Fixation

The Posterior Tail (7) of the Anterior Implant is attached to the anterior face of the uterine isthmus about 2 cm above the cervix with a single stitch of PROLENE suture.



Posterior Tail (7) of Anterior Implant

POSTERIOR REPAIR with Hysterectomy

Vaginal Incision and Vaginal Hysterectomy

A standard vaginal hysterectomy is performed through a pericervical incision. It is recommended that users identify and retain the uterosacral ligaments or other elements of the cardinal ligament complex. These structures can later either be interposed between the Posterior Implant and the vagina or attached to the edges of the Posterior Implant according to surgeon's preference. Care must be taken to close the peritoneum.

Posterior Vaginal Incision

The recommended incision for this repair is a complementary sagittal colpotomy of the lower / distal half of the vagina ending at the vulva. Alternatively, the dissection can be performed through a complementary transverse incision made at the junction of the perineal skin and the vagina. If a perineal repair is indicated, a diamond-shaped incision overlapping the lower half of the sagittal colpotomy and the posterior perineum is recommended.

Posterior Dissection

Care should be taken to accomplish separation of the rectum from the entire thickness of the vagina. Perform a dissection of the entire thickness of the posterior vaginal wall. Dissection starts from the vaginal incision and should be continued up to the apex of the vagina. Laterally, the dissection opens the pararectal spaces and follows the space between the rectum and the levator ani muscle until the sacrospinous ligament can be palpated. Generally, this dissection allows placement of a tool such as a Breisky retractor or other such instrument which will be useful during later activities. Further deep dissection should then be performed on both sides to expose or palpate the distal part of the sacrospinous ligament at the level of the ischial spine.

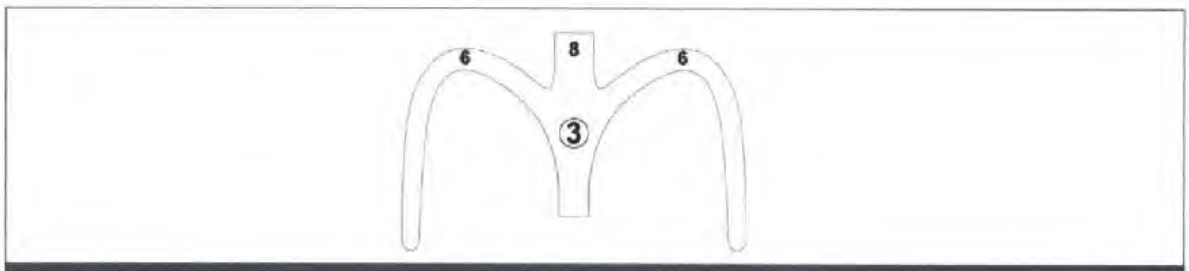
At this point, if required, a plication of the prerectal fascia in order to reduce the rectocele should be performed. Any required reductions of enteroceles should also be done at this time.

Preparation for Placement of the Posterior Implant

Two approaches for fixating the Posterior Implant are suggested.

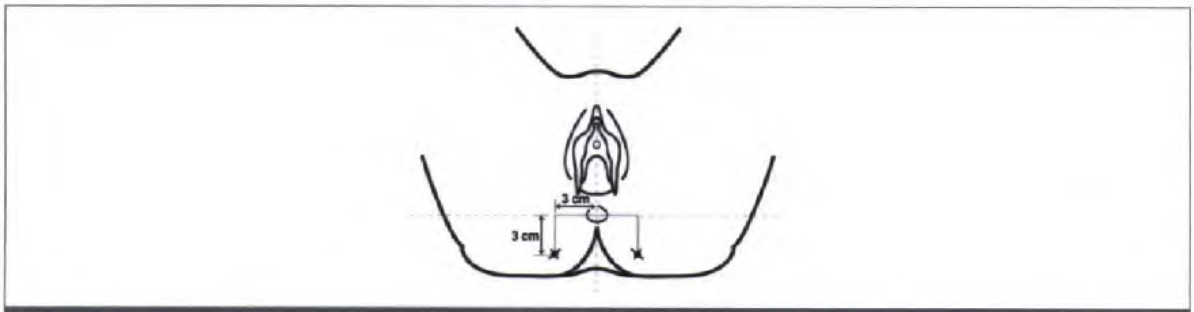
Transgluteal Fixation

The straps of the Posterior Implant are passed transgluteally and secured by passage of the straps through the sacrospinous ligament and coccygeus muscle.



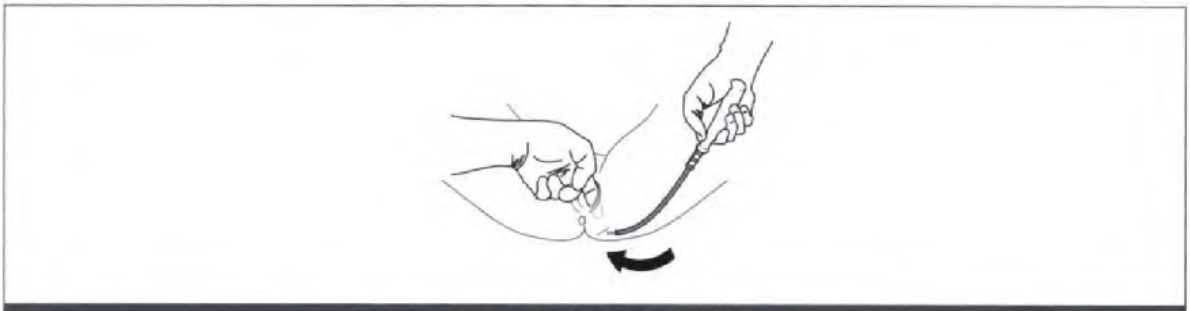
Posterior Implant

To accomplish this, a 4 mm cutaneous incision is made approximately 3 cm lateral and 3 cm down from the anus. If desired, sterile packing coated with lubricant may be inserted into the rectum first to ensure better appreciation of the position of the rectal ampulla.



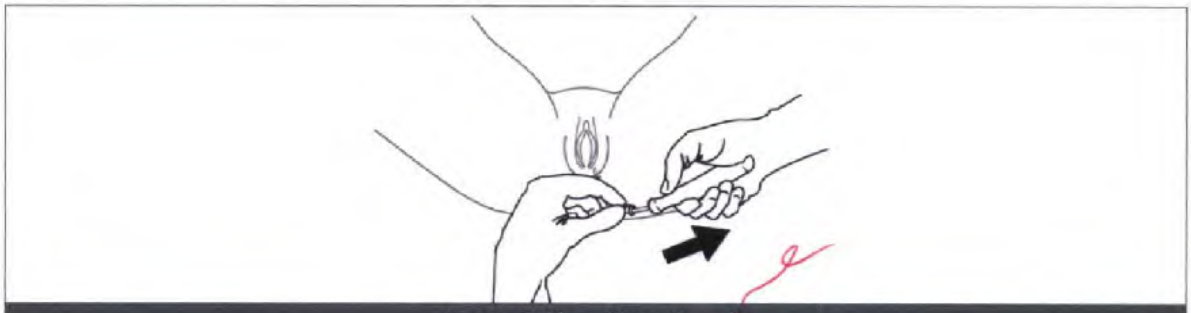
Posterior Incision

The Cannula-equipped Guide is inserted into the incision, passed through the buttocks, and continued below the plane of the levator ani muscle, constantly controlled by the fingers within the vaginal dissection. The rectum should be pulled back and kept at a distance, either manually, or by using a retractor to prevent damage from the device.



Insert Cannula-equipped Guide

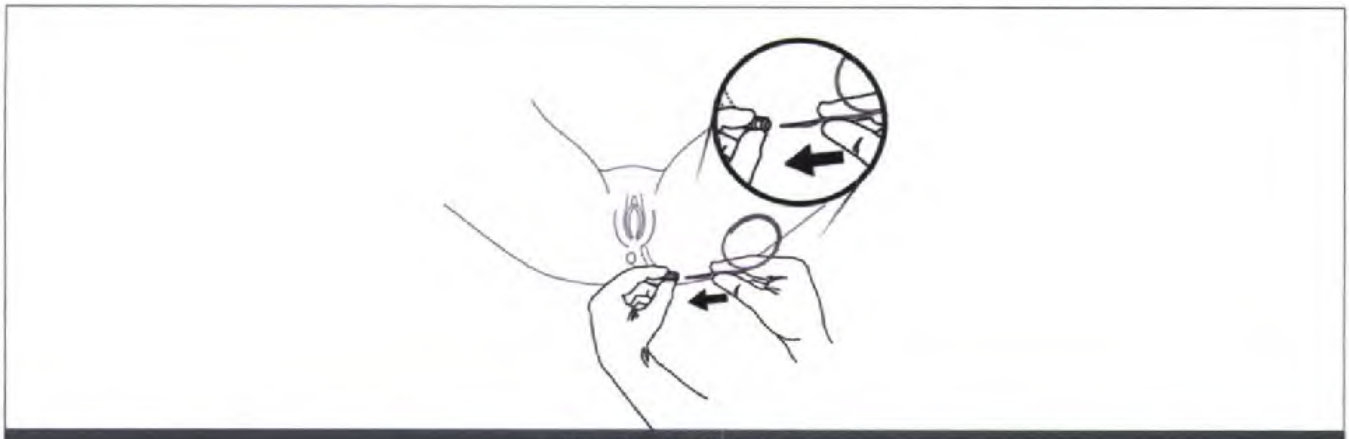
The device is advanced until it is in contact with the inferior side of the sacrospinous ligament approximately 3-4 cm medial to the ischial spine. The device is pushed through the sacrospinous ligament under digital control, thus exposing the tip of the Guide and Cannula. Once the distal tip of the Guide and Cannula exit the vaginal dissection, the Guide is removed, leaving the Cannula in place. Care should be taken to keep the Cannula in position as the Guide is withdrawn to ensure that the tip of the Cannula remains extended out of the tissue passage and the Cannula is not advanced further into the patient.



Remove Guide and leave Cannula

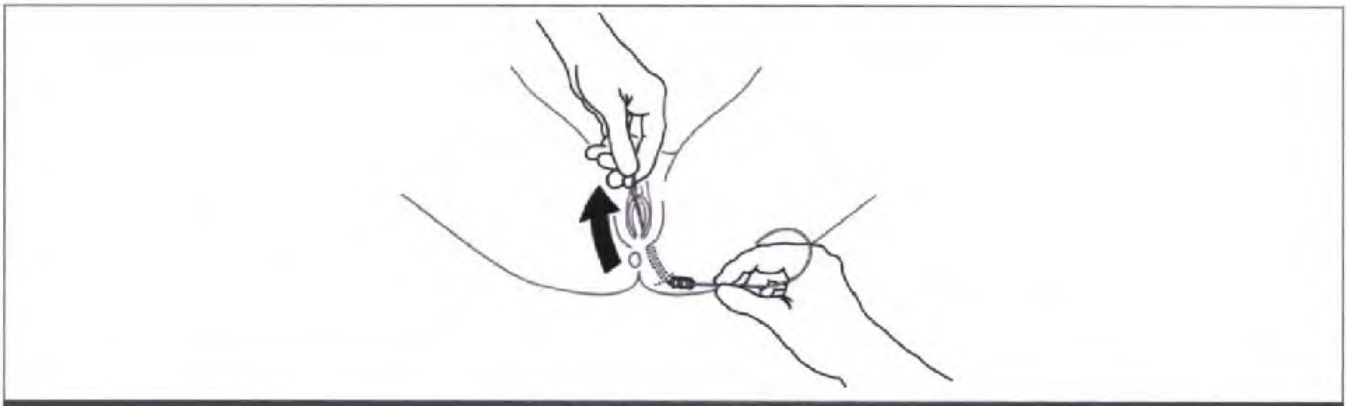
Once the Guide has been removed from the cannula, do not attempt to reinsert. Instead, remove the Cannula from the patient, reinstall the Guide, and then reinsert the Cannula into the patient.

Following placement of the Cannula, the Retrieval Device is passed down and advanced out of the distal end of the Cannula.



Pass Retrieval Device

The looped end of the Retrieval Device is then retrieved through the vaginal dissection and pulled out of the vagina with an instrument or a finger.



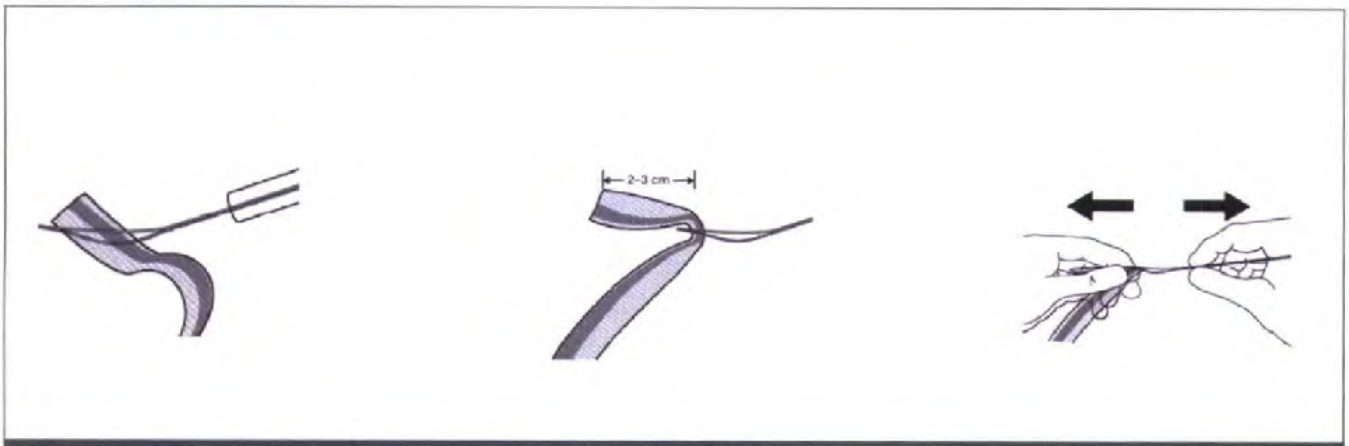
Retrieve the Retrieval Device

The proximal end of the Retrieval Device can then be passed through the loop and secured to the drape or a retractor with a hemostat, thus reserving the Retrieval Device for later use in pulling the Posterior Implant strap into position. Optionally, the Cannulas may also be secured when placed in order to limit movement as the other Cannulas are installed. Care should be taken to avoid movement of the Cannulas following placement.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

Placement of the Posterior Implant

To install the Posterior Implant, the distal ends of the straps are captured in the loops at the end of the Retrieval Devices. The loops are then pulled through the Cannulas to the proximal exit.

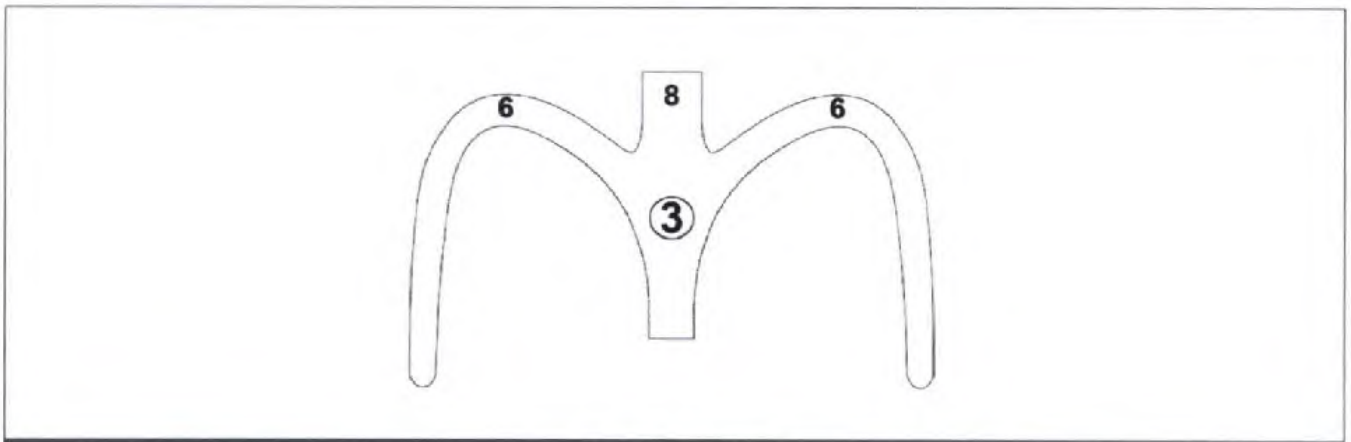


Capture distal ends

The Posterior Implant can be positioned once both straps have been retrieved. Optimally, the Posterior Implant will be positioned tension-free above the rectum with its lateral edges against the anterior face of the levator ani muscles.

Minor reductions in Posterior Implant length should be made at this point to ensure proper fit. If desired, sutures may be used bilaterally on the levator ani at the external edge of the Posterior Implant to ensure aid in positioning. A further fine adjustment of the tension and position of the Posterior Implant may be performed following closure of the vaginal incisions at the end of the procedure.

Alternatively, the straps (6) of the Posterior Implant may be fixated directly to the superficial aspect of the sacrospinous ligament. This can be accomplished by trimming the distal portion of these straps to the proper length and performing fixation with suture or alternative fixation means.



Posterior Implant

The Anterior Segment (8) of the Posterior Implant can be left free, or positioned above the Pouch of Douglas, or attached to the cardinal or uterosacral ligaments according to the surgeon's preference.

In the event that sutures, staples, or other fixation devices are used in conjunction with the mesh it is recommended that they be placed at least 6.5 mm (1/4") from the edge of the mesh.

Vaginal Closure and Final Adjustment

Closure of the vaginal incisions can now be made according to surgeon's preference. The straps should now be used to make any required additional fine adjustment to the Posterior Implant position, taking care to not place the mesh under tension. Following proper positioning, the Cannulas can be carefully withdrawn.

The ends of the straps extending out of the cutaneous incisions of the obturator foramen should be trimmed at the level of the dermis. These incisions are then closed according to surgeon's preference.

Posterior Repair with Uterine Preservation

The following includes important differences associated with the procedure when the uterus is preserved.

Posterior Vaginal Incision

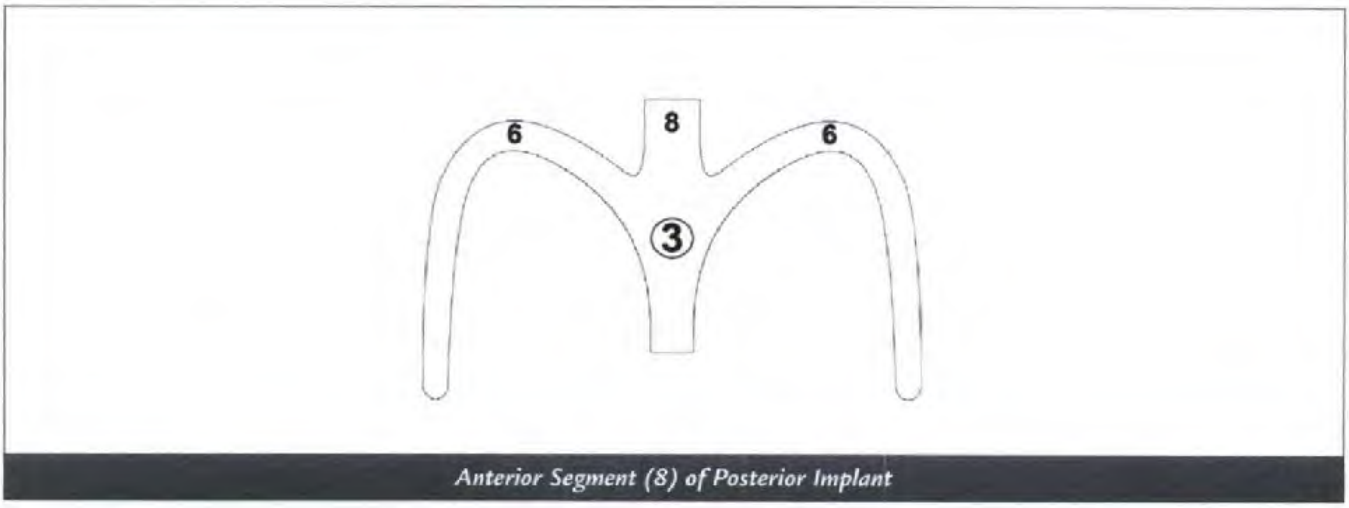
The recommended incision for this repair is a sagittal colpotomy of the lower half of the vagina ending at the vulva. Alternatively, the dissection could be performed through a transverse incision made at the junction of the perineal skin and the vagina. If a perineal repair is indicated, a diamond-shaped incision overlapping the lower half of the sagittal colpotomy and the posterior perineum is recommended.

Posterior Dissection

The posterior dissection is performed up to the uterine isthmus.

Posterior Mesh Fixation

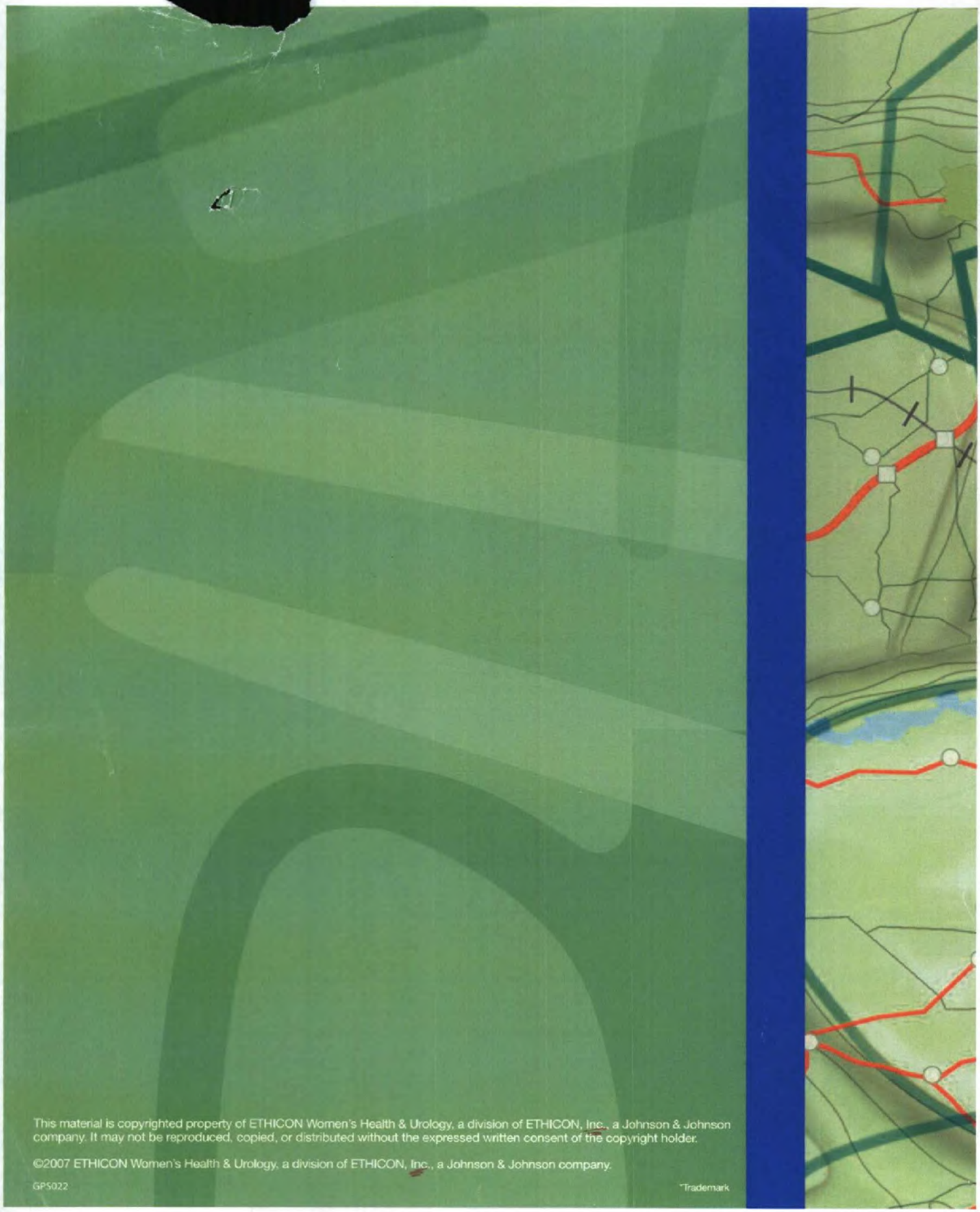
The Anterior Segment (8) of the Posterior Implant is attached to the posterior face of the uterine isthmus about 2 cm above the cervix with a single stitch of PROLENE suture.



Anterior Segment (8) of Posterior Implant

Associated Procedures

Whenever needed, a perineal repair or a suburethral sling for the treatment of stress urinary incontinence can be performed. The suburethral sling can be passed through the retropubic space or obturator foramen depending on surgeon's preference.



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